"Effectiveness of Nurse-Led Breathing Exercise Intervention Protocol on Labor Outcome among Pregnant Women in Selected Tertiary Care Hospitals of Bhopal – A Randomized Controlled Trial"

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In partial fulfilment of the requirement for the degree of

M.Sc. in Obstetrics & Gynaecological Nursing

By

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July 2024

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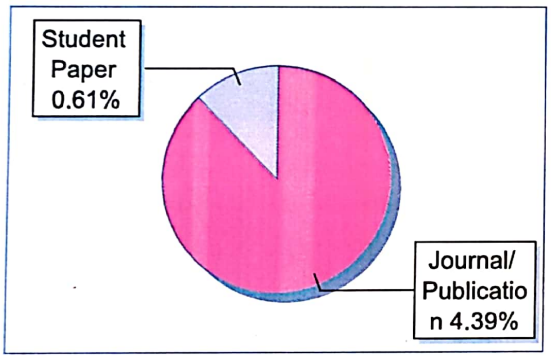

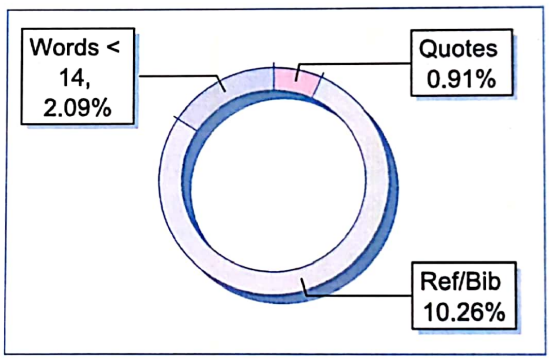

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AIIMS, Bhopal Institutional Human Ethics Committee- Student Research (IHEC-SR) in its 7th meeting held on 22nd February 2023 discussed your proposal titled **"Effectiveness Of Nurse Led Breathing Exercise Intervention Protocol on Labor Outcome among pregnant women in selected tertiary care hospitals of Bhopal - A Randomized Controlled Trial "** and evaluated it for suitability for your dissertation as required for fulfilment of MSc (Nursing).

Following members attended the meeting:

1. Prof. D. K. Pal, Former HoD Community Medicine, GMC, Bhopal……Chairperson
2. Prof. Rajnish Joshi, Professor of General Medicine, AIIMS, Bhopal……Member
3. Prof. Amit Agrawal, Professor of Neurosurgery, AIIMS, Bhopal……..Member
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5. Dr. Girish Bhatt, Addl. Professor of Paediatrics, AIIMS, Bhopal……Member
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8. Mr. Trivesh Goswami, Law Officer, AIIMS Bhopal,……Member
9. Dr. Shashank Purwar, Professor of Microbiology, AIIMS, Bhopal……Member Secretary

The decision of the committee is as follows:

The AIIMS, Bhopal IHEC-SR approves your research protocol. All research related activities must begin only after the date of this approval. The validity of this approval is till two years from the date of issuance. Please submit a closure report / renewal request before expiration of the validity for this approval.

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"***At times, our own light goes out and is rekindled by a spark from another person Each of us has cause to think with deep gratitude of those who have lighted the flame within us".***

Albert Schweitzer

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ABSTRACT

Background: Childbirth is intense and often metamorphic in nature for a women. In this process the women should feel safe, strong, capable and satisfied during labor & the birthing process as a whole. There are several non-pharmacological techniques available to alleviate the distress of women in labour particularly to reduce labor pain, its duration and improve the childbirth outcomes like relaxation, positioning, massage, breathing, etc. Considering the restricted birthing environment breathing may only be non-pharmacological comfort strategy that a pregnant women can resort to, which if taught can be practiced independently and hence the present study was undertaken to assess effectiveness of nurse-led breathing exercise intervention protocol on labor outcome among pregnant women.

Method :A Randomized controlled trial was conducted at the antenatal outpatient department in selected tertiary care hospitals of Bhopal (All India institute of Medical Sciences, Bhopal & Jaiprakash District Hospital, Bhopal) from September to December 2023. A total of 100 primigravida pregnant women from 35 weeks to 36weeks+6 days period of gestation without pregnancy related complications and chronic disease were recruited by convenient sampling technique and allocated randomly into intervention (n=50) and control group(n=50) by using SNOSE(Sequentially Numbered Opaque Sealed Envelope) technique. In addition to routine obstetrical care, the intervention group received a tailor-made nurse led breathing exercise intervention protocol which was administered from the recruitment till their respective onset of labor. The effectiveness of intervention was measured in terms of labor outcome (maternal outcomes and neonatal outcomes). The data was collected using structured

observational record to chart maternal & neonatal outcome, and Childbirth Experience Questionnaire.

Result: Both the group were homogenous in the characteristic in terms of sociodemographic variables (P>0.05). The intervention group (32.00±18.85) participants reported a reduced oxytocin drop rate compared to control group(50.05±15.86) (p<0.001). The total duration of labor, duration of 1st stage & 2nd stage of labor was significantly less in intervention group compared to control group and the intervention group participants reported better Childbirth experience score (53.52±6.37) than the control group (43.00±8.68) (p<0.001) .There was no significant difference in onset of labor, mode of delivery, nature of progress of labor and neonatal outcome between intervention and control group (p>0.05).

Conclusion : Through this study it is evident that nurse led breathing exercise intervention protocol has the potential to shorten the duration of labor, eliminate the need for augmentation of labor and facilitate the overall child birth experience of pregnant women.

Trial registration: CTRI/2023/09/057601

Keywords: Breathing exercise, antepartum, nurse led breathing exercise, labor outcome, maternal outcome, neonatal outcome, childbirth experience questionnaire, Lamaze breathing, complementary therapies, non-pharmacological method during labor

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16.	Participation information sheet Hindi
17	Participant consent form
18.	Master data sheet

LIST OF ABBREVIATIONS

Sl.no.	Abbreviations	Expansion
1.	NPM	Non- pharmacological management
2.	MMR	Maternal mortality rate
3.	WHO	World health organization
4.	PGE2	Prostaglandins E2
5.	PGF2α	Prostaglandins F2α
6.	VAS	Visual analogue scale
7.	RCT	Randomized controlled trial
8.	SNOSE	Sequentially numbered opaque sealed envelope
9.	POG	Period of gestation
10.	LMP	Last menstrual period

11.	EDD	Expected delivery date
12.	PPH	Post partum haemorrhage
13.	CEQ	Childbirth experience questionnaire
14.	PIS	Participant information sheet
15.	S-CVI	Scale content validity index
16.	SD	Standard deviation
17.	IHEC-SR	Institutional human ethical committee-student research
18.	Lop	Letter of permission
19.	CTRI	Clinical trial registration India
20.	LSCS	Lower segment caesarean section

LIST OF SYMBOLS

Sl.no.	Symbols	Expansion
1.	N	total no. of samples
2.	f	frequency
3.	%	Percentage
4.	χ^2	chi-square test
5.	df	degree of freedom
6.	¥	Fisher exact test

CHAPTER- I
INTRODUCTION

Background of the study

"Giving birth should be your greatest achievement, not your greatest fear."

— Jane Weidman

All Human life in this planet is born of women. In all cultures, giving birth to a child is considered as a vital and divine event. The joy and ecstasy of motherhood cannot be expressed in words. Childbirth stands as a transformative moment in the life of every expectant mother, a juncture where the journey from anticipation to the miracle of new life is traversed amidst a spectrum of physical sensations and emotional thresholds. Labor and childbirth represent a pivotal and transformative phase in a woman's life [(1),]yet it is often fraught with challenges that can encompass physical, emotional, and medical complexities.

Labour is an emotional experience and involves both physiological and psychological mechanisms.[(2)] The experience of labour is complex and subjective. Her maintenance of well-being throughout pregnancy plays a crucial role in enhancing uterine blood flow, supporting myometrial action, facilitating fetal descent, and promoting self-regulation during the labor process [(3)]. Due to the perpetuation of negative childbirth narratives over time, numerous women harbour apprehensions about the childbirth process. Consequently, this apprehension leads many women to distrust their own body's capabilities [(4).]

The process of childbirth holds lasting effects on a woman's health and overall well-being,[5]The childbirth experience significantly influences the development of positive self-esteem [6], emotional attachment to the baby, smoother adaptation to the role of motherhood [7,8], and future encounters with childbirth,[8]experiencing a negative childbirth experience may alter women's decisions about future pregnancies.[9] The major factors that affect childbirth experience is mothers own ability and strength, care by midwives, feeling of safety and supportive environment during labor .[10] The memories of past childbirth, negative stories heard from others, and the physical and psychological facets of the birth environment can influence women's childbirth experiences [11–13].

Systematic review on coping strategies for labor reports that women who use coping strategies encompass enhancements in self-belief or confidence and decreases in pain severity, fear, anxiousness, and the duration of labor [14]. Insufficient preparation for labor often amplifies a woman's experience of pain.[15] Women experience stress, fear and anxiety during childbirth. During delivery, excessive pain leads to increased fear, making a woman more sensitive to pain.[16] The concept of the fear-tension-pain cycle arises (figure 1), When the body experiences pain or stress, it triggers the release of chemicals like catecholamines, activating the fight-or-flight response. This physiological reaction includes increased breathing rates, which counteract the hormone oxytocin, ultimately slowing down the progression of labor. Additionally, this response reduces oxygen supply to the fetus and suppresses the production of endorphins [17]

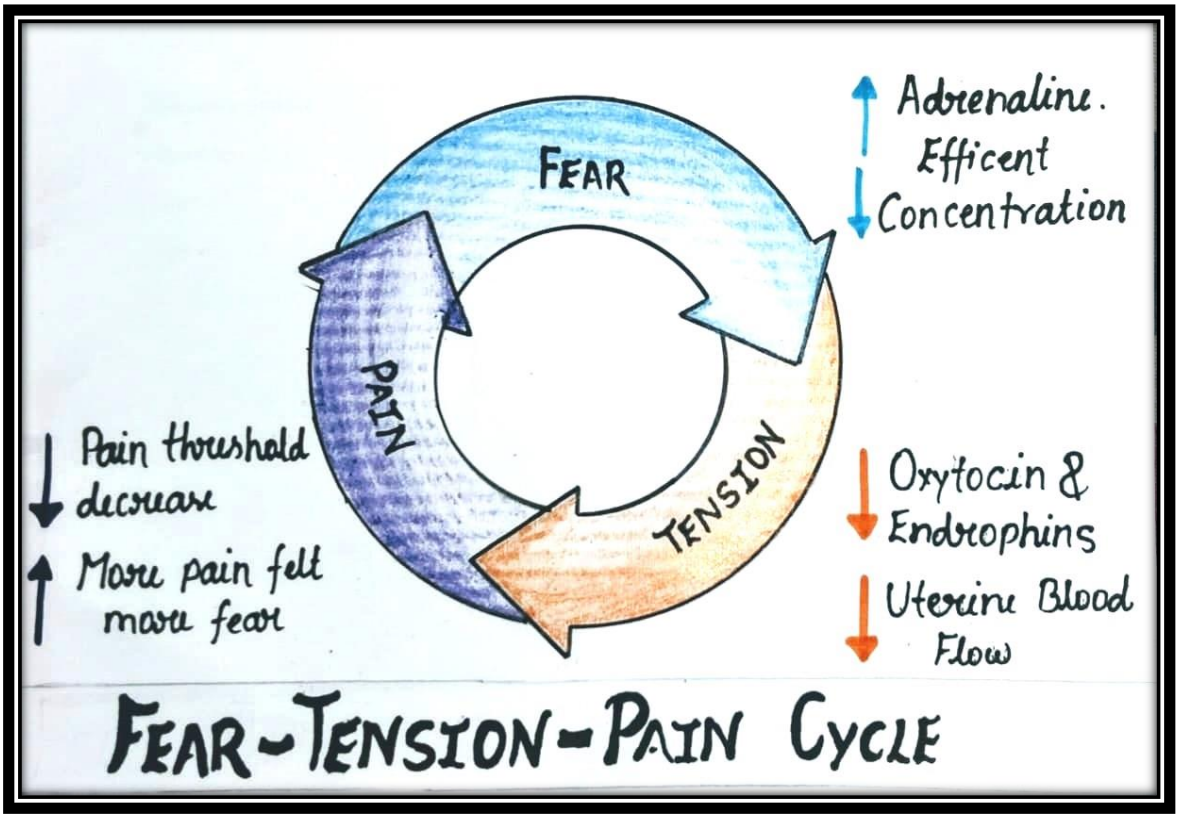

Figure 1: Fear tension pain cycle of labor

(Adapted from your Downtown doula-finding comfort during labor)[18]

As stated by Lynne Bluff, national coordinator of the Childbirth Educators' Professional Forum, "Birth resembles a dance. Understanding the steps enables women to relax, embrace sensations, feel the rhythm, and confidently navigate labor's natural progression for a beautiful birthing experience." While childbirth is universally recognized as a significant medical event, there is considerable emphasis on promoting natural birthing practices with minimal intervention. Therefore, it becomes essential to educate women about the regular biological processes and antenatal techniques that aid in effectively managing labor pain. This approach aims to enhance labor outcomes while minimizing intervention during childbirth.

A wide range of both pharmacological and nonpharmacological labour pain techniques and comfort measures are currently available for pregnant women. Pharmacological methods were highly effective; however, they were also linked to increased adverse effects like nausea, vomiting, and dizziness. In some instances, it might result in occurrences of instrumental delivery, fetal distress, cesarean section, urinary incontinence, motor nerve blockade, hypotension, and fever and lower satisfaction rates.([19,20] Non-pharmacological pain management (NPM) during labor encompasses methods aimed at enhancing comfort, supporting relaxation, assisting the woman in coping with labor pain, and averting her distress[21] various self-comfort methods such as relaxation, guided imagery, acupressure, aromatherapy, breathing techniques, hydrotherapy, temperature therapy, movement, massage, and music. Women are advised to utilize these techniques as they are non-invasive and seemingly safe for both mother and baby.[22] Utilizing these approaches during childbirth not only assists in acquiring effective coping skills but also contributes to fostering a positive labor experience.[23]

Considering the restricted birthing environment breathing may only be non-pharmacological comfort strategy that a pregnant women can resort to, which is one of simple, cost effective and if taught can be practiced independently. Focused breathing diverts attention from pain, help in relaxation and allowing the expectant mother to deliver while remaining conscious and attentive.[22,24] Focused and deliberate breathing techniques not only aid in fostering concentration but also contribute to a reduction in the perception of pain during labor. Simultaneously, the practice of calm and controlled breathing enhances a sense of fluidity and adaptability, fostering a feeling of synchronization with the birthing process, it also enhance the ability to cope with uterine contractions, and allow the uterus to function more efficiently.[25] Moreover, proper breathing patterns play a pivotal role in ensuring an adequate oxygen supply for both the

expectant mother and the fetus, thereby supporting their physiological needs throughout the labor process.[17]

A retrospective descriptive survey involving forty-six women who participated in childbirth preparation classes aimed to identify the favored and effective non-pharmacological pain relief methods. The findings indicated that deep breathing techniques were identified as the most effective pain-relieving practice during labor, closely followed by relaxation, acupressure, and massage.[23]

A clinical trial carried out to test the role of an efficacy-enhancing instructional intervention in upholding self-efficacy for childbirth and coping ability during labor on 113 primigravid women at 33-35 weeks of gestation where mothers demonstrated significantly greater levels of self-efficacy ($p < .000$), lower observed anxiety ($p < .001$, early stage and $p = .02$, second stage) and better coping during labor ($p < .01$)

Antenatal education aids in alleviating the fear associated with childbirth, while relaxation techniques assist in easing tension.

Therefore, providing expectant mothers with information, support, diverse resources, and effective tools empowers them to make informed choices that support a healthy pregnancy and delivery.

Need of the study

Peaceful pregnancy and birth of a healthy baby are the ultimate desires for every childbearing woman. Improving maternal health remains a significant global health challenge, showing minimal advancements as of 2015 [26]. Globally every 60 second , a woman dies in pregnancy or during childbirth[27]. Maternal mortality rate of India shown Significant Decline from 130 in 2014-16 to 97 per lakh live births in 2018-20[28] (figure 2), and in Madhya Pradesh MMR is 173 [28]. India contributes to 25% of debility-adjusted life-years lost due to maternal conditions alone which is a grave condition[29]

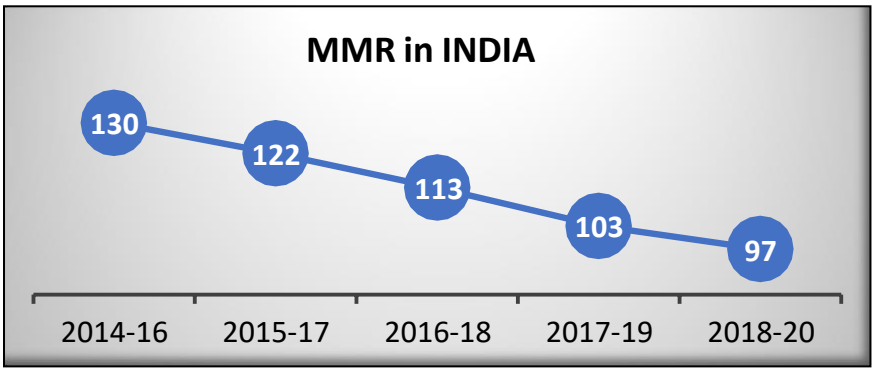

Figure 2: Maternal Mortality Rate In India[28]

The World Health Organization (WHO) advocates the implementation of relaxation techniques, such as breathing exercises, and supports midwife-led continuity of care models for managing labor pain. Additionally, the WHO discourages the routine use of labor augmentation as a standard practice in intrapartum care to promote a positive childbirth experience.[30] Providing continuous support during labor may enhance outcomes for women and infants, potentially leading to higher rates of spontaneous vaginal birth, shorter labor duration, and reduced occurrences of cesarean and instrumental vaginal births. Moreover, it may result in lower usage of analgesia, both

overall and regionally, fewer instances of low five-minute Apgar scores, and a reduction in negative perceptions about the childbirth experience.[31] One of the best ways for women to experience positive childbirth is to be cared for by a supportive midwife.[32]

Throughout history, educators have focused on techniques aimed at alleviating pain and fostering relaxation during childbirth. A wide array of non-pharmacological methods is accessible to women in labor [23], among which breathing stands out as an extensively available relaxation technique that can be effectively employed during childbirth.

During labor when women are instructed in labor, may find it challenging to adhere to instructions due to the intensity of pain experienced. However, through consistent practice during pregnancy, it is anticipated that women will instinctively respond similarly during actual contractions in labor, aligning with Pavlov's theory of conditioned response.[33], Hence, there exists a compelling necessity to instruct and emphasize the practice of breathing exercises during the antenatal period.

Collaboratively, obstetrician-gynaecologists, in partnership with midwives, nurses, patients, and their support network during labor, can aid women in achieving their labor and childbirth objectives [34]. Hence, there arises a necessity for a comprehensive and integrative nursing intervention aimed at enhancing labor outcomes.

The systematic review on the effectiveness of skilled breathing and relaxation technique during antenatal education on maternal and neonatal outcomes: reports improve maternal outcome, increased self confidence and self efficacy. However more explanation and research is needed [35]

The birthing encounter ought to be a remarkable and positive event for all mothers. Therefore, breathing exercises aim to enhance labor outcomes by minimizing unwarranted interventions, safeguarding maternal autonomy, and empowering women to achieve self-mastery during childbirth.

There is a need to be a global shift normalizing vaginal birth and providing the foundations which make it more achievable, such as continuity of care and high-quality independent birth education. The antenatal mother and family members need knowledge about the components of healthy pregnancy, the process of labor and birth. Improved knowledge about how normal labor occurs to have positive child birth experience. Midwives play a major role in upgrading the knowledge about antenatal exercises to all antenatal women.

Therefore, looking at the added benefits, safety and cost-effectiveness of the intervention, and researcher's interest to bring about a stereotype shift from restrictive birthing environment to relaxing birthing experience, it is a high time to increase good stories that talk about labour full of sensation, strength and joy with minimal intervention. the study aimed at finding the effectiveness of one simple non-pharmacological method, Nurse Led breathing exercises intervention Protocol on the outcome of labor among pregnant women.

Research Question

1. Is there any effect of nurse-led breathing exercise intervention Protocol on labor outcome ?
2. Is the labor outcome of the pregnant women associated with the education, occupation, residence, religion, type of family, social support, smoking habit, pregnancy planned?

Research Problem

Effectiveness of nurse-led breathing exercise intervention Protocol on labor outcome among pregnant women in selected tertiary care hospitals of Bhopal – A Randomized Controlled Trial.

Objective of the study

Primary Objective

1. To develop and administer nurse led breathing exercise intervention protocol to the Interventional group.
2. To assess the effect of nurse led breathing exercise intervention protocol on labor outcomes in terms of maternal and neonatal outcome among pregnant women.

Secondary Objective

3. To find association between labor outcome with selected demographic variables among pregnant women.

Hypothesis of the study

H01: There is no difference in maternal outcome among pregnant women of interventional group after the administration of Nurse led breathing exercise intervention protocol at 0.05 level of significance as measured by maternal outcome sheet and childbirth experience questionnaire.

H1: There is significant difference in maternal outcome among pregnant women of interventional group after the administration of Nurse led breathing exercise intervention

protocol at 0.05 level of significance as measured by maternal outcome sheet and childbirth experience questionnaire.

H03: There is no significant association between selected socio-demographic variables and maternal outcome at 0.05 level of significance

H02: There is no difference in neonatal outcome among pregnant women of interventional group after the administration of Nurse led breathing exercise intervention protocol at 0.05 level of significance as measured by neonatal outcome sheet.

H3: There is significant difference in neonatal outcome among pregnant women of interventional group after the administration of Nurse led breathing exercise intervention protocol at 0.05 level of significance as measured by neonatal outcome sheet.

H04: There is no significant association between selected socio-demographic variables and neonatal outcome at 0.05 level of significance

Operational definitions

Effectiveness- In this study, effectiveness refers to the extent to which nurse-led breathing intervention Protocol has a positive impact on the labor outcomes among pregnant women will be assess by structured tools and records .

Nurse led breathing exercise intervention protocol: In present study it refers to structured intervention protocol designed by a nurse, involving a series of interventions provided to the pregnant women who are at or above 35 weeks of gestation but below 37 weeks of gestation, onwards till completion of third stage of labor. The intervention

protocol includes a tailor-made video, demonstration, pictorial leaflet depicting the breathing exercises with all relevant instructions. Reinforcement of the exercises was ensured using 'WhatsApp group' to send voice reminder or message twice daily to perform breathing exercises. Daily home compliance to this intervention was checked using a compliance chart given to pregnant women. During the subsequent antenatal visits of the pregnant women emphasis made to clear any doubts and to ensure the breathing exercises were performed correctly at home. Following which the participants according to their stage of labor and contractions will be encouraged to perform the breathing exercises.

Labor outcome: In the present study Labor outcome is refers to the selected maternal and neonatal outcome.

Maternal outcome includes, period of gestation at the onset of labor, onset of labor, Nature of progress of labor need for augmentation, mode of delivery, nature of vaginal delivery, nature of expulsion of placenta, total duration of labor, duration of 1^{st} stage (after 5cm of cervical dilation) of labor, 2^{nd} stage, 3^{rd} stage of labor, any sign of PPH and childbirth experience.

Neonatal outcome includes status of newborn born, APGAR score at 1 minute & 5 minutes of birth, presence of any birth complications.

Pregnant women: In present study It refers to primigravida women who has crossed or is at 35 weeks of gestation but is less than 37 weeks of gestation.

Delimitation

1. The study is delimited to only two tertiary health care centres of Bhopal.
2. Primigravida pregnant women between gestational week 35 to 36 weeks +6 days of gestation with no pregnancy complication.
3. Only limited to pregnant women available at the time of data collection.

Conceptual framework

The labor experience is multifaceted, subjective, and often entails significant pain, particularly for first-time mothers.

Supportive care during labor aims to alleviate the perception of pain for the laboring patient. Techniques such as backrubs, sacrum support, abdominal effleurage, and repositioning are employed for this purpose. While breathing techniques may aid in pain prevention, once pain is perceived, additional interventions are required to interrupt the cycle. Therefore, breathing techniques are considered a purposeful activity rather than standalone supportive care. [36]

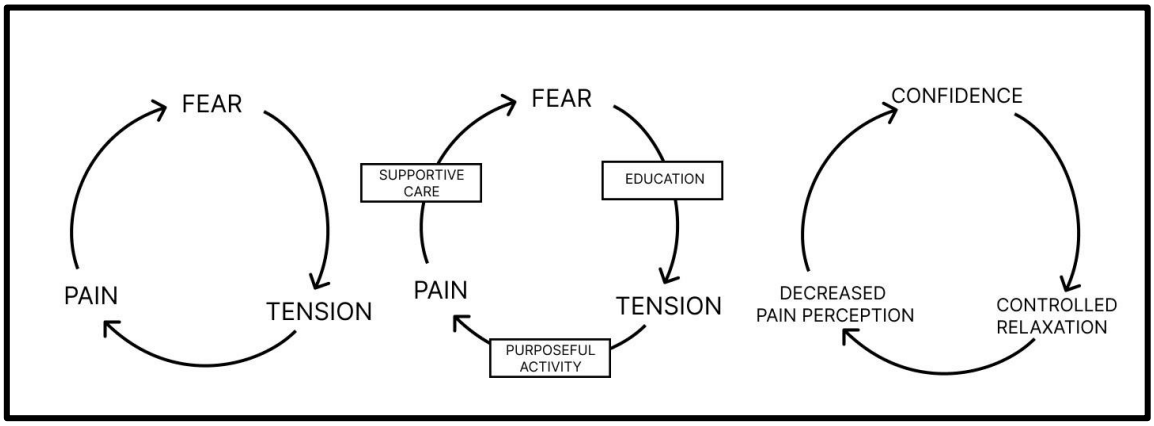

Figure 3: Conceptual model for intervention in pain in labor [36]

The presence of a caregiver dedicated to providing continuous support is essential for laboring women. Although the antepartum period is optimal for education about labor, early labor presents opportunities for learning due to heightened receptivity. Brief yet informative explanations about the purpose of contractions and bodily processes can empower women to actively participate in their labor. Understanding sensations reduces fear, enabling women to perceive them differently and potentially alleviate pain.[36]

Figure 3 clearly explains how breathing exercises aid in reducing pain and breaking the fear-tension-pain cycle, which is crucial for preventing complications. With this in mind, the nurse-led breathing exercise intervention protocol was implemented, drawing upon the concepts of Wiedenbach's theory of "The Helping Art of Clinical Nursing."

Helping people in need is the profession's main instrument, and nursing is frequently seen as an art rather than a science. Though everyone has different coping strategies, in trying times people could need help from others to get by, take care of their basic needs, work out problems, get well, and eventually live in harmony.

Ernestine Wiedenbach's theory of "The Helping Art of Clinical Nursing" served as the theoretical framework for this study, focusing on the primary objective of assisting women in identifying and fulfilling their needs.[37] The theory delineates **nursing** as the education aimed at discerning patients' needs for aid by observing and determining whether they necessitate support from healthcare professionals.

A **patient** is a person who is open to receiving assistance from the healthcare system in any form. Care, direction, and instruction are examples of help.

A patient's **need for help** is defined as an aid that, in the patient's opinion, helps them regain or increase their capacity to handle circumstances that have an impact on their health.

In addition to acting, a nurse also thinks and feels what the patient needs. A nurse applies their knowledge to their work. Clinical nursing consists of the following four components:

- philosophy
- purpose
- practice
- art

The **philosophy** of nurses refers to their attitude on life, their beliefs, and how those mirror reality. Purpose is grounded in philosophy, and philosophy is reflected in purpose.

The goal of planned activities is to accomplish the **purpose**, which is what the nurse or midwife wants to accomplish for the benefit of the client as a whole.

Practice entails nursing actions guided by perspectives and strategies aimed at fulfilling the client's needs for assistance. Three essential elements for effective practice include knowledge, judgment, and skills. Knowledge encompasses practical, theoretical, or experiential activities observed in practice. Clinical judgment refers to a nurse's ability to make informed decisions based on theory and connect them to desired outcomes. Effective judgment results from the careful integration of intellect and emotions, evolving alongside knowledge. Nursing skills are executed to achieve favorable outcomes rather than merely completing the task. Skills encompass a range of actions characterized by

coordinated movements, precision, and adept utilization of oneself. Identification, intervention, and validation are three practice components directly associated with patient care.

The **art** of nursing encompasses recognizing clients' needs and concerns, establishing objectives and action plans, and applying knowledge and skills to achieve desired results.

Identifying clients' needs involves observing their discomfort, discerning the root cause of their distress, and devising solutions to address their issues. Pregnancy represents a period where mothers require care, affection, and a positive outcome, thus establishing a situation driven by necessity.

At the core of the nursing profession lies a central purpose that reflects nurses' caregiving philosophy. In the context of this study, the primary objective is to enhance delivery safety and improve maternal and neonatal outcomes by upholding respect for life, dignity, autonomy, and individuality of the mother.

The request for assistance from other healthcare team members constitutes the provision of aid. This entails recognizing the need for assistance, selecting an appropriate skill, and ensuring patient acceptance of the intervention.

The five basic realities that influence central purpose are:

- Agent
- Recipient
- Goal
- Activities
- Framework

1. The agent refers to the researcher tasked with delineating objectives, such as instructing antenatal women in breathing exercises starting from 35 weeks of gestation, and subsequently implementing these objectives accordingly.
2. The recipient refers to the woman who is motivated to engage in breathing exercises with the aim of improving the likelihood of a favorable outcome.
3. The goal or directed outcomes represent the desired achievements that the nurse aims to attain.
4. Activities or methods employed to accomplish or fulfill the anticipated outcome, such as utilizing breathing exercises, serve as the means to achieve the desired result.
5. The framework encompasses various components including human, environmental, professional, and organizational resources. The environment pertains to healthcare settings providing antenatal and intranatal care to women. Professionals refer to healthcare practitioners working in outpatient antenatal clinics, as well as intrapartum nurses responsible for selecting and monitoring women throughout the study stages. Organizational facilities represent the available resources provided to women during the antenatal and intranatal periods to enhance safe delivery and improve maternal and neonatal outcomes.

The prescription entails any nursing activity conducted to serve a central purpose. Appropriate nursing actions are identified to develop a care plan aligned with the central purpose. The proposed nursing intervention involves providing tailor made video on antenatal breathing techniques to low-risk singleton pregnant primigravid women after 35 weeks of gestation, encouraging them to practice these exercises twice daily for 15 minutes, and conducting follow-ups during labor. This nursing intervention was voluntary, and mothers consented mutually to engage in the breathing exercises both during the antenatal period and labor.

Validation refers to the confirmation that the client's need for assistance has been fulfilled due to the provided support. In this context, validation occurred when women engaged in breathing exercises after 35 weeks of pregnancy and throughout various stages of labor, demonstrating tangible signs of comfort and proficiency. This observable evidence indicates that the need for assistance has been addressed effectively.

The nursing theory of the helping art provides contemporary women, who often lead busy lives, with strategies to reconnect with their innate intuitive wisdom. This enables them to gradually discover their increasing competence in managing childbirth.

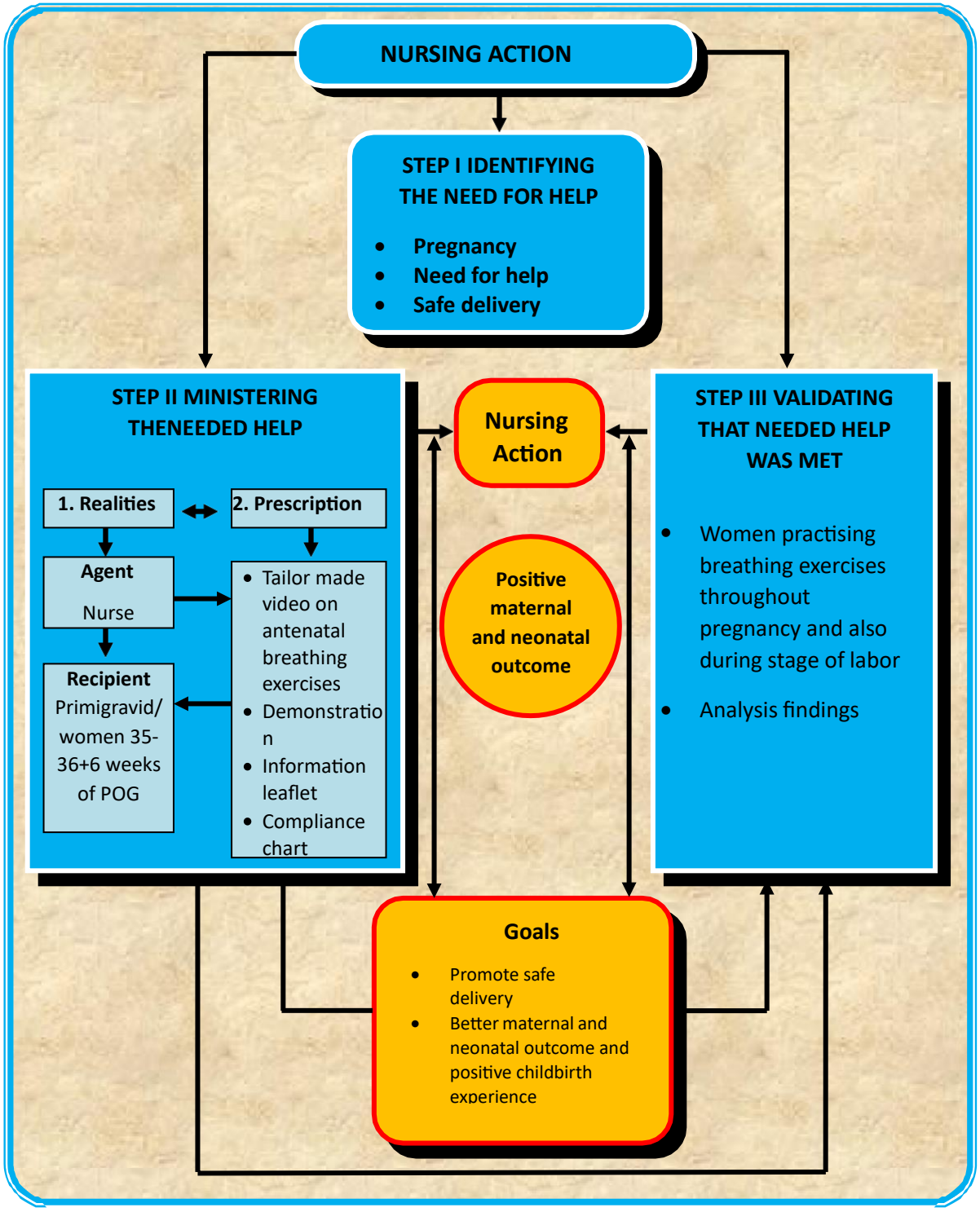

Figure 4: Conceptual framework based on Weidenbach's theory

Summary

This chapter dealt with background, need of study, problem statement, and objective of the study, hypothesis, operational definition, , delimitation, conceptual framework

CHAPTER- II

REVIEW OF LITERATURE

Introduction

A literature review is an assembly of sources that establishes the foundation for future investigation. It is deemed essential for research endeavors and encompasses the process of locating, choosing, meticulously assessing, and succinctly summarizing existing knowledge pertaining to a specific subject.[38] . Review of literature equip and empower the researchers to theorize the research ideas.

According to Abdellah and Levine, the material gathered in literature review should be included as a part of the research data, since it influence the problem and research.[39] Burns and Grove defined it as an organized written presentation of what has been published on a topic by the scholar.([40]

Examining the literature aids in determining the suitable methodology, crafting research instruments, analyzing data, and linking findings across studies to advance knowledge within a particular field. The researcher conducted a thorough literature review on the research subject to gain a deeper understanding of the issue and gather pertinent information necessary for structuring the study in a rigorous manner, aiming to attain the desired outcomes.

Aims and Questions of the Review

The aims of the literature review were to pinpoint and assess the related research papers around physiology and neuro- endocrinological process associated with labor, factors

influencing labor outcome, existing non- pharmacological intervention during labor, effect of breathing exercise on labor, role of nurses in labor.

The literature search was based on four focused questions:

1. What are the key physiological processes and neuro- endocrinological event associated with labor and childbirth process in pregnant women?
2. What are the factors that influence labor outcome and childbirth experience?
3. What are the existing non- pharmacological and complimentary therapies in labor management ?
4. Is breathing exercise intervention effective in improving the labor outcome?

Seach strategy

To identify specific and relevant literature, keywords were used, such as breathing exercise, antepartum breathing exercise, Nurse Led intervention, labor outcome, maternal outcome, neonatal outcome, childbirth experience, uncomplicated pregnancy, low-risk and women. Synonyms of keywords, truncations (*, #), wildcards (?) and different word spellings were considered when searching for studies. Keywords were searched for in different electronic databases that contain the vast majority of studies within the nursing and midwifery fields. Databases included the Cumulative Index of Nursing and Allied Health Literature (CINAHL), EBSCO HOST, Cochrane Library, Medline (Ovid platform), PsycINFO, Scopus, PubMed. Bibliographies of the retrieved studies were reviewed to facilitate easy access to additional appropriate studies. Grey literature was searched through Google Scholar.

Initially, the search strategy began with single keyword searches and then Boolean operators (AND/OR/NOT) were added to combine words to retrieve all relevant studies.

The Boolean operators were used as -AND, OR, NOT such as “antepartum breathing exercise” OR “antenatal breathing exercise” OR “Lamaze breathing” AND “delivery” OR “labor outcome” OR “maternal outcome” OR “duration of labor” OR “childbirth experience”, other terms such as intervention for labor management, midwife led intervention for labor management. The following word or keyword combinations were utilised in MeSH (Medical Subject Heading) searches: The topics covered in this article include labour, obstetrics, parturition, delivery, breathing exercises, diaphragmatic breathing, Complementary therapies, respiration, women, gravidity, pregnant women, labour stages I, II, and III, duration of labour, mode of delivery, and childbirth experience.

An extensive review of the literature was conducted, encompassing articles with full text, abstracts, free full text, documents, clinical trials, systematic reviews, protocols, meta-analyses, and studies available freely and published in English from the years 2003 to 2023.The keywords used were Breathing exercise, antepartum, midwife led breathing exercise intervention, labor outcome, maternal outcome, neonatal outcome, childbirth experience, Lamaze breathing, complementary therapies, non-pharmacological method during labor.

The review included 41 research articles, comprising 5 systematic reviews, 10 review articles, 12 experimental studies, 7 descriptive studies, and 1 qualitative study.

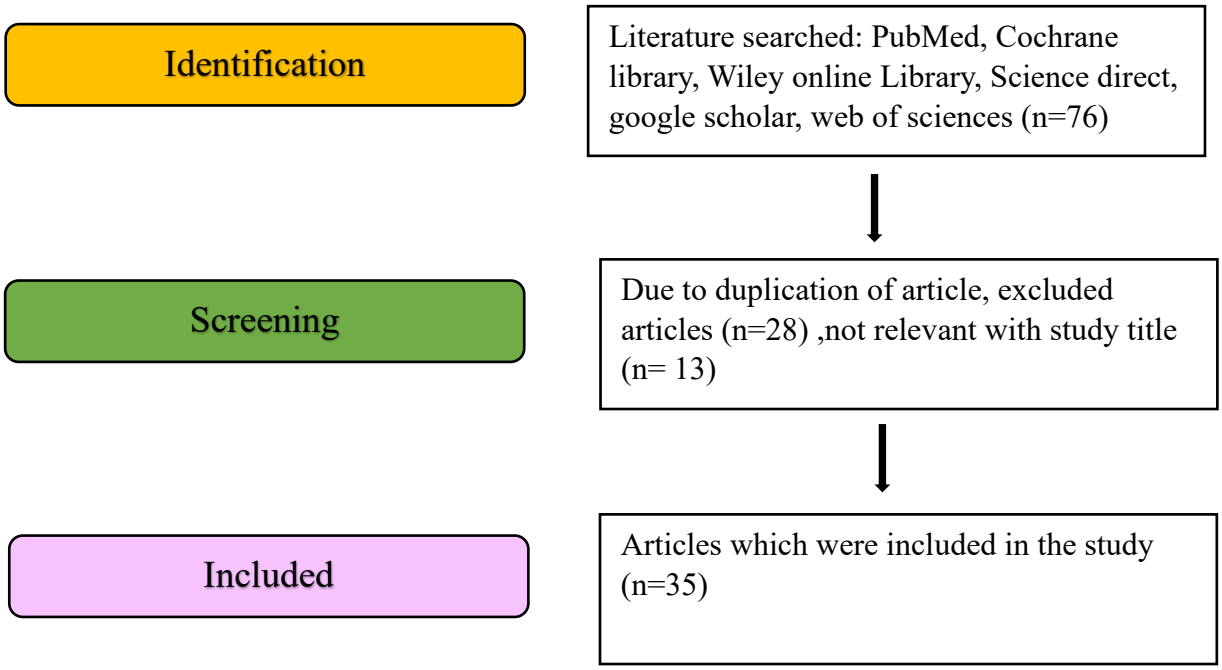
Identification
Literature searched: PubMed, Cochrane library, Wiley online Library, Science direct, google scholar, web of sciences (n=76)
Screening
Due to duplication of article, excluded articles (n=28) ,not relevant with study title (n= 13)
Included
Articles which were included in the study (n=35)

Figure 5 : Schematic representation of search strategy

The retrieved literature has been organized and presented under the following headings:

1. Physiological and neuro endocrinological onset and events of labor
2. Factors influencing labor outcome and childbirth experience
3. Non-pharmacological or complimentary therapies during labor and childbirth
4. Effectiveness of breathing exercise during pregnancy and labor

1. Literature related to physiological and neuro endocrinological onset and events of labor

Labor represents a natural physiological progression marked by a coordinated series of alterations within the myometrium, decidua, and cervix. This process unfolds gradually across days to weeks, characterized by a crescendo of changes occurring rapidly over hours, ultimately culminating in the expulsion of the fetus and placenta.([41])

Labor encompasses a complex physiological phenomenon entailing the harmonization of hormonal elements (endocrine, paracrine, and autocrine) governing continuous modifications within the uterine cavity. Throughout pregnancy, a delicate synchronization occurs between the forces maintaining uterine quiescence and those triggering uterine contractions.[42]

Labor denotes the natural process through which a fetus is delivered from the uterus. It necessitates consistent, rhythmic uterine contractions, growing in frequency, strength, and duration.[43] In typical childbirth, these fundamental components are interconnected and culminate in the natural breaking of the amniotic sac and subsequent birth of the baby. The following conditions signify a normal labor process, also known as Eutocia:

1) Spontaneous in onset and at term
2) With vertex presentation
3) Without undue prolongation
4) Natural termination with minimal aids
5) Without having any complications affecting the health of the mother and the baby

The equilibrium between forces maintains the closure of the cervical os, preventing uterine emptying, while timed pressure aids in softening and dilating the cervix. These adjustments must be positioned to facilitate uterine emptying, promoting the physiological onset of labor.[43]

Estrogen

During pregnancy, there is an increase in estrogen activity, with levels rising as the pregnancy advances, mainly produced by the placenta. Estrogen stimulates several changes in the myometrium, such as increased levels of PG E2 and PG F2α, heightened

oxytocin receptor presence, activation of calcium channels, α-adrenergic agonist effects, formation of connexon units, and establishment of gap junctions in the uterus. Furthermore, a decline in estrogen levels contributes to cervical softening.[43]

Progesterone

Uterine activity is orchestrated by the coordinated action of progesterone, influenced by estrogen. Elevated fetal production of dehydroepiandrosterone sulfate (DHEA-S) and cortisol hinders the conversion of fetal pregnenolone to progesterone, leading to a decline in progesterone levels preceding labor. The shift in the estrogen-progesterone ratio is thus pivotal in initiating labor.[43]

Animal research indicates that a decrease in progesterone levels triggers the onset of labor. Conversely, several human studies suggest that withdrawal of progesterone action initiates' labor.

Prostaglandins

They are vital factors that aid in promotion and maintenance of labor. Raised prostaglandin levels are seen in the uterus and membranes before and during labor.(44) The amnion, chorion, decidual cells, and myometrium contribute to prostaglandin synthesis. Prostaglandin production is stimulated by various factors, including increased estrogen levels, glucocorticoids, cytokines, mechanical stretching, infection, vaginal examinations, and membrane separation or rupture. Maternal decidua primarily secretes PGF2α, which induces uterine contractions by directly stimulating the uterine myometrium and enhancing the response to oxytocin, as well as promoting the formation of gap junctions. Conversely, PGE2 of fetoplacental origin facilitates cervical softening and dilation, ultimately leading to spontaneous rupture of the fetal membranes.([43]

Oxytocin Changes in the vagina and cervix result in increased levels of oxytocin which in turn leads to activation of oxytocinergic system.(45) Throughout pregnancy, these neurons maintain a state of dormancy due to the influence of central opioids, which inhibit premature oxytocin release. Oxytocin, upon activation of phospholipase C (PLC), stimulates the release of prostaglandins E2 and F2α in the fetal membranes, initiating the flow and discharge of calcium from intracellular stores. [43].

Pregnancy and childbirth are profound life-altering experiences for women and their families. Pregnancy represents a phase of enduring neurological adaptations, encompassing a complex interplay of endorphins, prolactin, steroid hormones, neurosteroids, oxytocin, vasopressin, and catecholamines.

Oxytocin:

Commonly referred to as the "hormone of love," serenity, and bonding, oxytocin plays a crucial role in coordinating the physical processes of labor, childbirth, and breastfeeding through its timely release from the pituitary gland.

During relaxation phases, oxytocin's neuromodulatory effects dampen the functioning of the sympathetic nervous system and its branches within the autonomic nervous system, resulting in decreased levels of stress hormones like adrenaline and noradrenaline.

This suppression further results in a decrease in other stress hormones, including corticotrophin-releasing hormone, adrenocorticotropic hormone, beta-endorphins, and cortisol, due to the inactivation of the hypothalamic-pituitary-adrenal pathway.

The decline in these hormones proves immensely beneficial to women during the intranatal, postnatal, and lactation periods. The surge in oxytocin levels immediately after

birth not only benefits women and their newborns by reducing the risk of excessive bleeding and facilitating longer maternal adaptation but also promotes the release of prolactin, fostering feelings of calm, connection, and biological bonding.[46]

Beta-endorphins

Beta-endorphins, a set of peptides or opioid substances, primarily affect the central nervous system, inhibiting nerve function and inducing analgesic effects while activating the brain's reward center.

Respiration involves the activation of voluntary mechanisms (controlled by the cortex) and involuntary mechanisms (affected by emotional, metabolic, neural, and endocrine components). While breathing is a critical function, it is not directly regulated by specific hormones but rather influenced by various hormonal factors. Progesterone is among the hormones that stimulate respiration, enhancing ventilation by heightening the sensitivity of the respiratory center to carbon dioxide levels. ([47])

A research study conducted on 50 pregnant women aimed to investigate the analgesic impact of exercise during labor. The findings revealed that 84% of the women experienced reduced pain during uterine contractions, which were observed to be more frequent and regular both before and after exercise. Additionally, elevated levels of beta-endorphins were detected following exercise ($p<0.01$). Based on these results, the study concludes that engaging in exercise during labor enhances uterine contractions and serves as a form of analgesia attributed to the release of beta-endorphins.[48]

In a separate investigation, 28 expectant mothers reported that respiratory autogenous training (RAT) influenced beta-endorphins levels during labor and delivery, leading to a hypoalgesic effect and relaxation of vaginal muscles during childbirth.[45]

Levels of beta endorphins increase in placenta and amniotic fluid during pregnancy. Relaxation helps in the modulation of endorphins [31]

Physiological changes during pregnancy:

During the initial weeks of pregnancy, respiratory parameters increase, including minute ventilation, tidal volume, alveolar ventilation, and respiratory rate. Elevated progesterone levels at term decrease PCO2, leading to reductions in expiratory reserve volume, functional residual capacity, and residual volume, resulting in upward displacement of the diaphragm. Increased inspiratory capacity due to higher inspiratory reserve volume and tidal volume causes vascular, edematous, and fragile respiratory mucous membranes. These parameters typically return to pre-pregnancy levels within 6 to 12 weeks postpartum.[25]

Deep breathing triggers the parasympathetic nervous system, which opposes the physiological alterations observed during pregnancy, such as elevated heart rate, plasma volume & cardiac output, This leads to a physiological response marked by reduced blood pressure, heart rate, oxygen consumption, and metabolic rate. Additionally, deep breathing enhances neuroplasticity as an adaptive mechanism, improving motor control.[49]

Conscious control of breathing rate, to some degree, originates from higher brain centers. This action reduces the partial pressure of carbon dioxide in the blood, leading to peripheral vasodilation.[50]

Deep breathing expands the rib cage and elongates the spine, which proves advantageous as the fetus develops. It enhances oxygen uptake in the bloodstream, fostering relaxation, and aids in soothing an anxious or stressed mother during labor.

Influence of hormonal changes on breathing in pregnancy

Progesterone

The progesterone level gradually rises during pregnancy, reaching from 25 ng/mL at six weeks to 150 ng/mL at 37 weeks. Progesterone heightens the reactivity of the central respiratory center to carbon dioxide levels. Additionally, progesterone affects the smooth muscle tone of the airways, resulting in bronchodilation. [51]

Estrogen

The increasing levels of estrogen during pregnancy impact the progesterone receptors.
, which increase both their quantity and their responsiveness in central neuronal respiratory-related areas[52]

Prostaglandins

Prostaglandins stimulate uterine smooth muscle activity throughout pregnancy and are found in every trimester. Prostaglandin F2α causes constriction of bronchial smooth muscle. leading to increased airway resistance, while prostaglandins E1 and E2 can have a bronchodilator effect.([51]

2. Literature related to Factors influencing labor outcome and childbirth experience

In a qualitative study by Nilsson [7] (2013), the focus was on describing the experiences and reflections of first-time mothers regarding their initial childbirth. Fourteen Swedish-speaking first-time mothers who had normal births, were not under the care of the authors, and had healthy infants upon hospital discharge were included. Written narratives were collected, and the analysis revealed a main theme: "To be empowered increases first-time mothers' chances for a positive birth experience." This overarching theme intersected with three categories: "To trust the body and confront the pain," "The interplay between body and mind during childbirth," and "Consistency of support." The findings indicated that when professionals responded to the individual woman's support needs, the likelihood of a positive birth experience increased.

Maternal childbirth experience in induced and spontaneous labour measured in a visual analog scale and the factors influencing it was undertaken by Adler K [53] (2020) conducted a comprehensive two-year cohort study. The study involved 18,396 deliveries, with 28.9% being induced and the remaining 71.1% spontaneous. Maternal satisfaction in the childbirth experience was gauged post-delivery using a Visual Analog Scale (VAS) score, with a VAS < 5 indicating a low childbirth experience score.The research revealed significant disparities in satisfaction levels between induced and spontaneous laboring women. A notably higher proportion of women who underwent labor induction expressed lower satisfaction with their birth experiences compared to those with spontaneous onset [7.5% (n = 399) vs. 3.2% (n = 420); $p < 0.001$]. Several contributing factors to poor childbirth experiences were identified, including primiparity [OR 2.0 (95% CI 1.6–2.4)], labor induction [OR 1.6 (95% CI 1.4–1.9)], caesarean delivery [OR 4.5 (95% CI 3.7–5.5)], operative vaginal delivery [OR 3.3 (95% CI 2.7-4.0)], post-partum haemorrhage

[OR 1.3 (95% CI 1.1–1.6)], and maternal infections [OR 1.7 (95% CI 1.3–2.4)]. These findings underscore the significance of various obstetric factors in influencing women's satisfaction levels during childbirth experiences.

With the purpose to evaluate the impact of personality, socio-demographic and obstetric factors on birth experience of healthy first-time mothers Larsson C. [54] (2011) took up to prospective cohort designed study. The study enrolled a sample of approximately 541 Swedish-speaking first-time mothers with normal pregnancies, ranging from gestational weeks 37 to 39.The study outcomes underscored significant associations between various factors and the birth experience of these first-time mothers. Specifically, a recollection of intense pain during childbirth, increased usage of postpartum analgesics, prolonged hospitalization, late-pregnancy worry, and elevated self-reported irritability were associated with more negative birth experiences. Conversely, the presence of high confidence in the midwife was linked to more positive birth experiences among these mothers. This research illuminates the multifaceted nature of childbirth experiences, highlighting the impact of both obstetric factors and emotional states on shaping the perceptions of first-time mothers during labor and delivery.

A study conducted in Sweden with aimed at evaluating the impact of obstetric interventions and complications on women's satisfaction with childbirth by Fakal M ([55],(2019), The study encompassed 16,775 women, each of whom had a recorded Visual Analog Scale (VAS) score.The findings revealed that the prevalence of dissatisfaction with childbirth, indicated by VAS scores ranging from 1 to 3, stood at 5.7%. Further analysis highlighted significant risk factors associated with dissatisfaction during childbirth. Notably, emergency cesarean sections exhibited a substantially increased

likelihood of dissatisfaction, with an adjusted odds ratio (OR) of 3.98 (95% CI 3.27-4.86). Additionally, postpartum hemorrhage of ≥2000 ml and a five-minute Apgar score below 7 were identified as factors contributing to dissatisfaction, with respective adjusted odds ratios of 1.85 (95% CI 1.24-2.76) and 2.95 (95% CI 1.95-4.47).

Correlational descriptive study conducted by Goodman et al[8] (2004) involving 60 low-risk postpartum women, aged 18–46 years, who had uneventful vaginal deliveries of healthy full-term infants at two medical centers in the southeastern United States.

The study gathered data using various measures, including The Labor Agentry Scale, McGill Pain Questionnaire, Mackey Childbirth Satisfaction Rating Scale, and a background questionnaire completed by the women. Obstetrical information was collected from medical records. The findings highlighted that personal control emerged as a statistically significant predictor of overall childbirth satisfaction (P = 0.0045). It was also significantly associated with satisfaction across various components, including self, partner, baby, nurse, physician, and the overall childbirth experience. This research underscores the significant role of personal control in shaping the satisfaction levels of postpartum women following vaginal deliveries, emphasizing its influence on multiple facets of the childbirth experience

Sweden antenatal women (2541) were recruited for longitudinal cohort study from all antenatal clinics in Sweden during 3 weeks spread over 1 year was conducted by Waldenström U et al.[9](2004) with the intention to investigate the prevalence and risk factors of a negative birth experience in a national sample. A specialized questionnaire was developed to assess women's overall experiences of labor and birth one year postpartum, alongside gathering data on potential risk factors during pregnancy and at the

two-month post-birth mark. The study revealed that 7% of the women reported having a negative birth experience. Several risk factors contributing to negative birth experiences were identified: Factors associated with unexpected medical issues, including emergency operative delivery, labor induction, labor augmentation, and infant transfer to neonatal care, Factors linked to the woman's social context, such as an unwanted pregnancy and lack of support from the partner, Factors related to the woman's emotional state during labor, such as perceived pain and a sense of lacking control, Factors more amenable to influence by healthcare providers, such as insufficient time allocated for the woman's questions during antenatal checkups, inadequate support during labor, and the administration of obstetric pain relief.

3. Literature related to non-pharmacological or complimentary therapies during labor and childbirth

In a RCT conducted by Jahdi F et al [56] (2016) in Iran, The aim was to assess how an antenatal yoga program affects the perceived pain during labor and the outcomes of delivery. Randomization of 60 primiparous women aged18-35 years old were done into antenatal yoga group and control group. Intervention comprised antenatal yoga regimen 60-minute guided yoga session, conducted thrice weekly, commencing at the 26th week of pregnancy. Participants' level of labor pain and discomfort were evaluated using a Visual Analog Scale (VAS) when cervical dilation reached 3-4 cm, with follow-up assessments conducted at 2 and 4 hours after the initial evaluation. The findings indicated that there were no significant differences observed in the administration of analgesia ($p = 0.2$), APGAR scores, and newborn birth weight ($p > .05$). However, a statistically

significant difference was noted in the duration of labor, specifically during the second and third stages (p =.04).

A meta-analysis was undertaken by Chaillet N et al [57] (2014), The study aimed to investigate non-pharmacological approaches for pain management during labor and their effects on maternal and neonatal outcomes. Their review, encompassing data from Embassy, MRCT, CINAHL, and MEDLINE databases spanning January 1990 to December 2012, focused on randomized controlled trials following Cochrane criteria. They contrasted these techniques with standard care and observed that interventions such as Gate Control (including movement, hydrotherepy, sacral massage, and position) and Diffuse Noxious Inhibitory Control (such as sterile water injection, acupressure, TENS, acupressure) were linked to decreased utilization of epidurals and heightened satisfaction among mothers during labor. Non-pharmacological approaches centered on CNS Control (e.g., education, attention diversion, support) and Standard care was significantly linked with elevated likelihood of various obstetric interventions. The study found that standard care was associated with increased rates of various obstetric interventions, including higher epidural use, cesarean deliveries, forceps or vacuum-assisted deliveries, oxytocin administration, and prolonged labor duration. Conversely, non-pharmacological methods that provided continuous support during labor were identified as most effective in reducing these interventions. These approaches not only helped alleviate pain but also improved maternal and neonatal health outcomes. Crucially, they offered significant benefits without causing harm to women or their infants

Smith and colleagues [58] (2006) conducted a comprehensive review to evaluate alternative and complementary therapies for pain management during labor and their effects on maternal and perinatal health. They conducted an extensive review of data from

various registers and databases up to July 2002, including the Cochrane Pregnancy and Childbirth Group trials register, Cochrane Controlled Trials Register, MEDLINE, EMBASE, and CINAHL. The review included randomized controlled trials comparing alternative therapies with placebo, no treatment, or pharmacological pain management during labor. The criteria for inclusion encompassed women in both stages of labor, irrespective of parity or labor induction. The analysis involved seven trials comprising 366 women that investigated various modalities of pain management: acupuncture (n = 100), hypnosis (n = 189 across three trials), aromatherapy (n = 22), audio-analgesics (n=25) , and music (n = 30). Findings indicated that acupuncture reduced the need for pain relief (RR 0.56, 95% CI 0.39 to 0.81), while hypnosis resulted in higher maternal satisfaction with pain management during labor compared to controls (RR 2.33, 95% CI 1.55 to 4.71). However, no significant differences were observed for aromatherapy, music, or audio analgesia.

Systematic review was undertaken by Simkin P et al [59] (2010), focused nonpharmacologic methods to alleviate labor pain and prevent suffering. They conducted thorough searches across electronic databases such as CINAHL, PUBMED, Cochrane Library, and AMED, to evaluate the efficacy of 13 non-pharmacological methods for pain management during labor. The review highlighted those certain methods displayed substantial evidence in reducing labor pain, such as continuous labor support, baths, and maternal movement and positioning. Acupuncture, transcutaneous electrical nerve stimulation (TENS), and hypnosis showed promise but necessitate further investigation to establish their efficacy. Yet, the efficacy of childbirth education, aromatherapy ,relaxation and heat and cold application breathing techniques, , acupressure, , music, and audio analgesia showed inadequate investigation or exhibited greatly inconsistent results, rendering it difficult to reach conclusive determinations regarding their effectiveness. In

general, the methods examined in the review garnered broad satisfaction among most users. However, further research is necessary to confirm the efficacy of diverse nonpharmacologic methods for alleviating labor pain and minimizing distress.

A group of Chinese researcher Chen Y et al [60] (2021) were done systematic review and meta-analysis of RCT focussing on efficacy of acupressure during labor and delivery. They searched major databases until January 31, 2018, identifying 13 randomized controlled trials (RCTs) encompassing 1586 enrolled patients. The analysis revealed that acupressure, when combined with standard procedures (ASP), significantly reduced pain sensation compared to sham acupressure with standard procedures (SASP) and standard procedures alone (SP). This analgesic effect was immediate and persisted for at least 60 minutes (all $p < 0.01$). Additionally, the acupressure group exhibited a shorter duration of labor, particularly in the first stage (SMD = -0.76, 95% CI = -1.10 to -0.43; $p < 0.001$; I2 = 74%) and second stage (SMD = -0.37, 95% CI = -0.59 to -0.18; $p < 0.001$; I2 = 0%). However, evidence regarding the reduction in Cesarean section rates was inconclusive. The use of pharmacologic agents (oxytocin and analgesics) did not differ between the ASP, SASP, and SP groups. Importantly, no adverse events were reported across these studies.

Lee SL et al [61] (2013) engaged in a study to verify the efficacy of warm showers on parturition pain and the birth experiences of women during the first stage of labor. A randomized controlled trial was adopted. Ninety-two participants were enrolled and allocated into two groups through block randomization, with 80 women completing the trial. The experimental group received warm shower bath interventions, lasting 20 minutes each. This included a 5-minute full body or lower back shower, followed by 15 minutes directing the shower water to their most comfortable body region, with the

flexibility to stand or sit. The water temperature was maintained at 37°C. Meanwhile, the control group received standard childbirth care.Using the Visual Analogue Scale for Pain (VASP) and the Labour Agentry Scale, the study assessed labor pain and birth experiences, respectively. Upon adjusting for demographic and obstetric data, women in the experimental group who underwent warm showers reported significantly lower VASP scores at 4-cm and 7-cm cervical dilations, along with more positive birth experiences compared to the control group.

With the purpose to determine the impact of plantar reflexology as an intervention on the severity of labor pain childbirth experience and the duration of labor stages amongst 90 women Moghaddam MJ et al (2021) Participants were divided into three groups: Intervention 1 (two 30-minute massages at the effective pain points for each sole), Intervention 2 (one 30-minute massage at the effective pain point and one at the heel for each sole), and Control (two 30-minute heel massages). Massages were administered at 4-cm and 7-cm cervical dilations. Labor pain severity and childbirth experience were evaluated using the Visual Analogue Scale and Labor Agentry Scale, respectively. The duration of labor stages was tracked using the Partograph chart. Results revealed significantly lower pain severity in Intervention Group 1 compared to the Control Group (AMD: −1.7; 95% confidence interval: −2.8 to −0.6; $p = 0.001$). However, no significant differences were found between Intervention Groups 1 and 2 ($p = 0.066$), or between Intervention Group 2 and Control ($p = 0.336$). There was a notable difference between groups in terms of the duration of the third stage of labor ($p = 0.04$). Yet, no significant distinctions emerged between groups concerning mean childbirth experience scores ($p = 0.217$), duration of the active phase ($p = 0.099$), and the second stage of labor ($p = 0.114$). In summary, the study indicated that plantar reflexology, specifically in Intervention Group 1, led to significantly reduced labor pain compared to the Control Group. However,

no substantial differences were observed between the intervention groups in terms of childbirth experience and durations of certain labor stages.[62]

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4. Literature related to effectiveness of breathing exercise during pregnancy and labor

Practising breathing in pregnancy leads to increased comfort during labor and post labor, reduced experience of labor pain and shorter duration of total labor time[63]

Randomized controlled trial conducted in Southern India with the purpose to explore the impact of antepartum breathing exercises on maternal outcomes during labor among primigravid women by Karkada S et al. [22] (2023) Eligible primigravid women were randomized into intervention and standard care groups. Eligible participants were randomized into intervention and standard care groups, both receiving standard obstetrical care. The intervention group was additionally trained in antepartum breathing exercises and encouraged to practice these exercises daily, including during the active stage of labor. The primary outcomes measured included the onset of labor, delivery type, labor duration, and the need for labor augmentation. Data were collected using the World Health Organization (WHO) partograph and structured observational records. Findings revealed that 98 (70%) primigravid women practicing antepartum breathing exercises experienced spontaneous onset of labor. The odds of spontaneous labor onset in the intervention group were 2.192 times higher compared to standard care (95% confidence interval: 1.31–3.36, $p < .001$). Additionally, the need for labor augmentation was minimal, and there was a reduction in the rate of caesarean deliveries ($p < .05$) based on the $\chi 2$ test. Moreover, the overall mean duration of labor was significantly shorter in the intervention group compared to the standard care group ($F(1)= 133.800$, $p < .001$).

Systematic review and meta-analysis was undertaken by Issac A et al (2023), focusing on assessing the efficacy of breathing exercises on the duration of labor. They searched electronic databases including MEDLINE, CINAHL, EMBASE, Web of Science, SCOPUS, and Clinical Key for randomized controlled trials and quasi-experimental studies published in English from January 2005 to March 2022, reporting on the impact of breathing exercises on labor duration. The primary outcome analysed was the duration of labor, while secondary outcomes included anxiety, duration of pain, APGAR scores, episiotomy, and mode of delivery. Meta-analysis was performed using RevMan v5.3.The review encompassed trials with a total of 1418 participants, ranging from 70 to 320 individuals per study. The average gestational weeks of the participants across the trials was 38.9 weeks. The findings indicated that breathing exercises contributed to shortening the duration of the second stage of labor in the intervention group compared to the control group.[64]

A randomized controlled trial conducted by Boaviagem A et al [65] (2016) involving sixty low-risk primigravid mothers aimed to evaluate the efficacy of different breathing patterns during labor, spanning from 37 to 41 weeks of gestation, on labor pain, distress, and satisfaction. Findings indicated no significant difference in labor pain (MD 0.23, 95% CI -0.738 to 1.184, p = 0.564) or maternal distress (RR 0.87, 95% CI 0.318–2.40, p = 0.599). However, there was an improvement noted in maternal satisfaction (MD 2.57, 95% CI 0.843–4.291, p = 0.005). Consequently, the study suggests that the adoption of breathing patterns during labor should be guided by the individual preferences and choices of women.

A team of Indian academics, Narendran S et al. [66] (2005), conducted research to ascertain the effectiveness of breathing, one of yoga's fundamental poses. This descriptive study,

conducted in southern India, looked at the pregnancy outcomes of 335 moms who were recruited at the antenatal clinic in Bangalore between the ages of 18 and 20 weeks gestation. Preterm delivery was less common ($p < .0006$), baby weights ≥2500 grammes ($p < .01$) and problems like isolated intrauterine growth restriction ($p < .003$) and pre-eclampsia with IUGR ($p < 0.025$) were also significantly different, according to the study.

In order to assess the effect of breathing exercises on maternal discomfort, labour duration, and first-minute APGAR scores during the second stage of labour, a randomised controlled experiment was carried out in Turkey. via Yuksel H. et al. [67] (2017) 250 pregnant women participated in the trial, which featured random groupings into two groups: the control group (CG; n = 125) and the intervention group (IG; n = 125).While the control group did not get any instruction in breathing techniques, the intervention group was trained in them and practiced them during the second stage of labour. The age range of the participants was 18 to 42 years, with a mean age of 23.2 ± 4.2 years. The baseline parameters of age, occupation, education level, and smoking habits were similar in both groups ($P > 0.05$).Findings indicated, The intervention group's mean Visual Analogue Scale (VAS) scores for pain were substantially lower (88.2 ± 6.3) than those of the control group (90.5 ± 7.0) ($P < 0.001$), according to the results. Furthermore, there was a significant difference ($P < 0.001$) in the duration of the 2nd stage of labour between the intervention group (369.6 ± 92.0 seconds) and the control group (440.7 ± 142.5 seconds). The mean first-minute APGAR scores for the two groups, however, did not differ significantly (IG: 8.84 ± 0.50 vs. CG: 8.73 ± 0.89). (P greater than 0.05).

Research gap analysis

The review of literature highlighted the existence gaps in literature including:

The childbirth experience significantly influences the development of positive self-esteem, emotional attachment to the baby, smoother adaptation to the role of motherhood, and future encounters with childbirth . Experiencing a negative childbirth experience may alter women's decisions about future pregnancies, an important outcome yet not thoroughly investigated regarding the effects of intervention bundles on it.

Majority of literature illustrates the effect of antenatal breathing exercise on pain, the limited literature on effect of antenatal exercise on duration of labor, nature of delivery, neonatal outcome and also the child birth experience of mother.

Not elucidated that the enhancement in childbirth experience in interventional group after intervention is admittedly only due to Nurse led breathing exercise intervention protocol not due to any other confounding variable.

Limited studies were available that independently assessed the effect of a complete set of breathing exercises on labor outcomes. Some studies only considered focused breathing and deep breathing, lacking comprehensive examination of the complete set of breathing exercises' impact.

Few studies have investigated the various methods of teaching antenatal exercises to mothers while also focusing on compliance. Among these studies, a limited number exclusively utilized video materials, while others relied on traditional classes.

Suggestion for further researches to increase the generalizability of the research finding

Summary of the chapter

This chapter deals with review of literature related to the stated problem. The researcher was able to obtain understanding of the subject under investigation and establish the necessity for the study with the aid of this literature review. It also assisted the researcher in designing the investigation, creating a tool for the data collection process, and creating an analytic strategy.

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CHAPTER- III
MATERIALS AND METHODS

Methods and materials are the important framework for description of research approach ,variables (independent and dependent), research setting, population, sample and sampling techniques, plan and procedure for the data collection, analysis and presentation.[68]

An analytical approach to resolving the research challenge is through research technique. The methodology specifies the general framework for setting up the procedure for gathering reliable and relevant data for the study.[69]

This chapter covered the study's methodology in detail, outlining the research strategy, design, variables, study setting, population, sample, and sampling technique, as well as the creation and description of tools, description of intervention, ethical consideration, feasibility testing (a pilot study), data collection process, and data analysis plan.

Research approach and Research design

The research approach is a plan to determine method of data collection, analysis and interpretation. It is the basis strategy adopted by researcher to develop information that is accurate and interpretable.[70]

The research approach entails a systematic depiction of the strategy used to investigate the phenomenon under study, encompassing a detailed explanation of data collection methods, analysis, and interpretation. It may take the form of a structured approach, such

as quantitative research, an unstructured approach, such as qualitative research, or a combination of both known as mixed methods.(68).

The objective of the study was to quantify the effect of Nurse Led Breathing Exercise intervention protocol on labor outcome among pregnant women, hence **quantitative approach** was preferred.

The research design is a blueprint to carry out research study with control on factors that may treat the validity of findings. The selection of the research design in the most important step as to provide the framework for the study. (70)

The study evaluated the effectiveness of nurse led breathing exercise intervention protocol on labor outcome among pregnant women in selected tertiary care hospitals of Bhopal. Accordingly, **prospective, randomized, controlled, trial was adopted for the study.** The randomized controlled trials are the best-known strategy to avoid the selection and confounding bias in the clinical research.

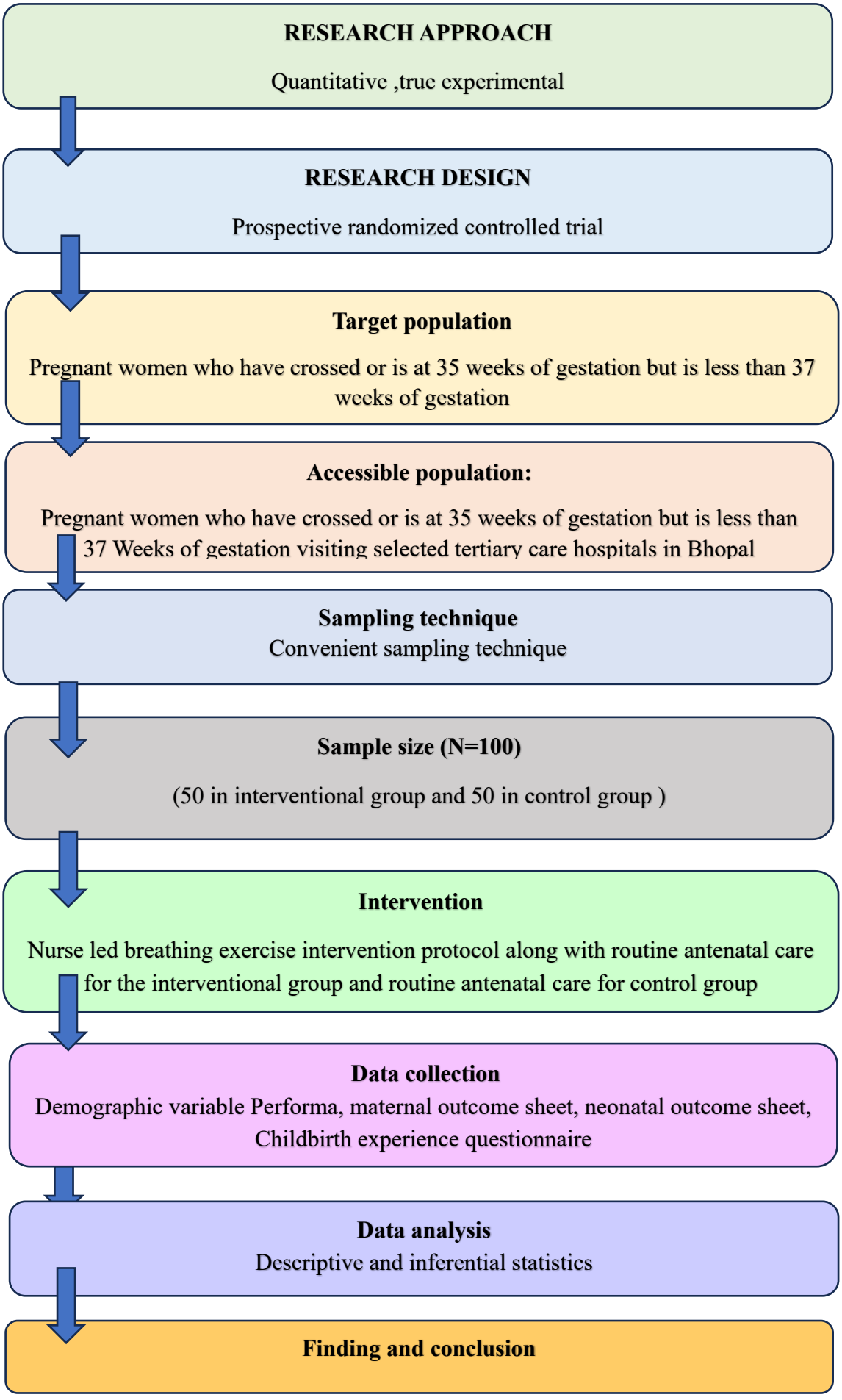
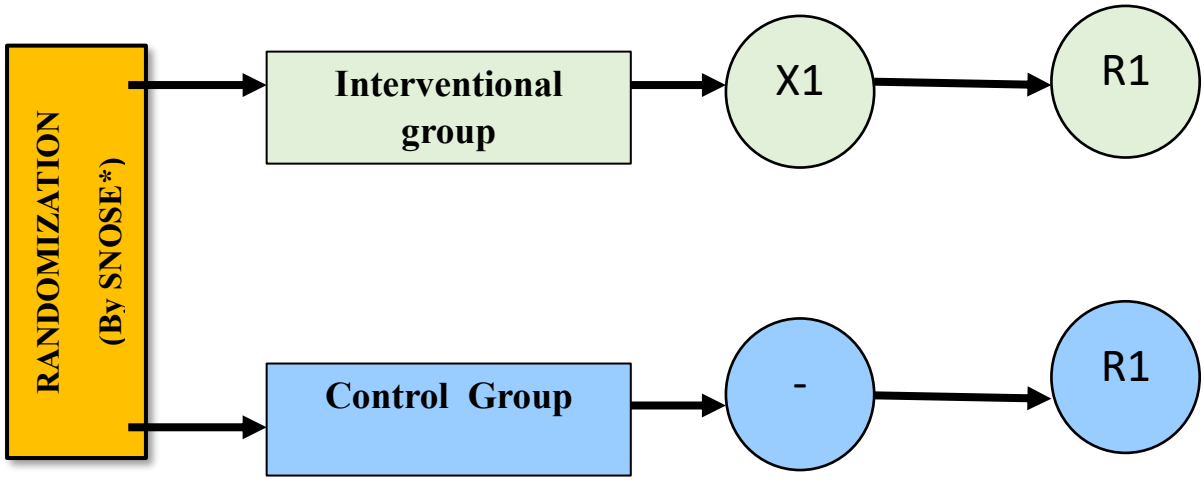

RESEARCH APPROACH
Quantitative ,true experimental
RESEARCH DESIGN
Prospective randomized controlled trial
Target population
Pregnant women who have crossed or is at 35 weeks of gestation but is less than 37 weeks of gestation
Accessible population:
Pregnant women who have crossed or is at 35 weeks of gestation but is less than 37 Weeks of gestation visiting selected tertiary care hospitals in Bhopal
Sampling technique
Convenient sampling technique
Sample size (N=100)
(50 in interventional group and 50 in control group)
Intervention
Nurse led breathing exercise intervention protocol along with routine antenatal care for the interventional group and routine antenatal care for control group
Data collection
Demographic variable Performa, maternal outcome sheet, neonatal outcome sheet, Childbirth experience questionnaire
Data analysis
Descriptive and inferential statistics
Finding and conclusion

Figure 6: Schematic representation of research methodology



*SNOSE: sequentially numbered opaque sealed envelope

X1: Nurse led breathing exercise intervention protocol

- : Routine Obstetric care (antenatal care and health talk)

R1: Labor outcome

Fig 7: Symbolic representation of study design

Randomization

Randomization is one of the cornerstones of the RCT.[71] and a true random allocation procedure should be used.

The process of randomization was meticulously executed to ensure unbiased allocation of participants into the intervention and control groups. It involved the use of sealed, opaque envelopes, each consecutively numbered, the sealed opaque envelope was used for allocation concealment. These envelopes contained information about the group to which the participant would be assigned, based on a pre-established, computer-generated random sequence of numbers. The randomization followed a 1:1 ratio between the

intervention and control groups.

To maintain the integrity of the randomization process, the envelopes were prepared in advance by an individual not directly involved in the study. This person was responsible for both generating the random sequence and assembling the envelopes. With the use of sequentially numbered opaque sealed envelopes (SNOSE), an outpatient nurse further divided the individuals in the OPD into groups. By entrusting this task to an independent party, the risk of bias or manipulation in the allocation process was minimized.

1st Another person generated random table no. and opaque sealed envelope prepared

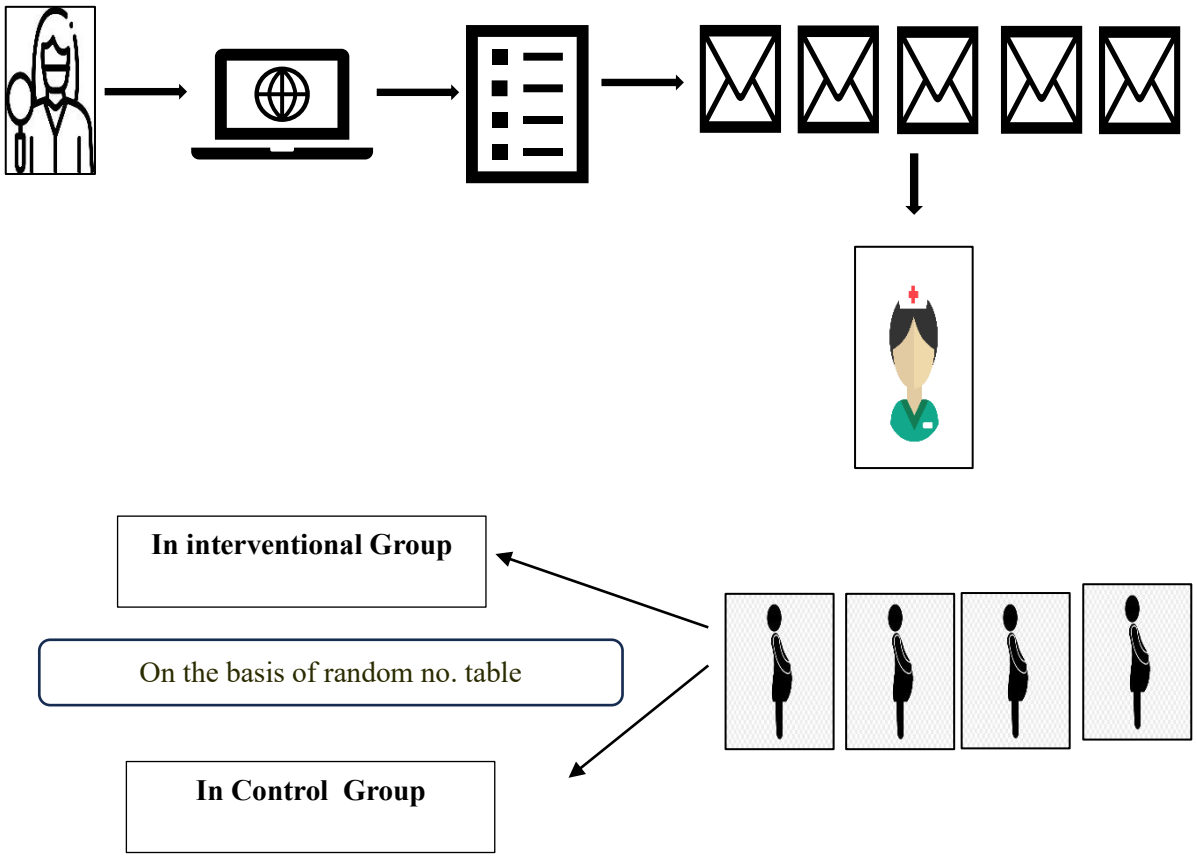


Figure 8: Pictorial representation of randomization process (SNOSE*)

* Sequentially numbered opaque sealed envelopes

Variables under study

Variables are qualities, properties or characteristics of person, thing or situation that change or vary and are manipulated or measured in research.[68]

Independent variable: the independent variable is the condition or characteristic that the researcher manipulates or control in an attempt to ascertain their relationship to the observed phenomena. In the present study the independent variable is a Nurse Led Breathing Exercise Intervention Protocol.

Dependent variable: are the condition or characteristic that appear, disappear or change as the researcher introduces, removes or changes the independent variable. In the present study the dependent variables is the

Maternal outcome:

- Onset of labor
- Nature of progress of labor
- Need for augmentation
- Mode of delivery
- Nature of vaginal delivery
- Nature of expulsion of placenta
- Total duration of labor
- Duration of 1st stage (after 5cm of cervical dilation) of labor
- 2nd stage of labor
- 3rd stage of labor
- Any sign of PPH
- Childbirth experience

Neonatal outcome:

- Newborn status at birth
- APGAR score at 1 minute & 5 minutes of birth
- Any birth complications.

Research setting

The setting is the location in which the researcher is conducted in order to collect the data, It denotes the specific place and circumstances where data collection for the study occurred.[68]

The research took place at selected tertiary hospitals of Bhopal, Madhya Pradesh, India. Bhopal, a district of Madhya Pradesh consists total area of 2,772 km2 and with a population of 23,68,145([72]

The researcher selected the setting for the data collection was Obstetrics and Gynaecology (OBG) units: Antenatal OPD and Labor room of AIIMS Bhopal and Jai Prakash District hospital, Bhopal, Madhya Pradesh.

AIIMS Bhopal is a tertiary level medical college hospital having 960 beds. The Clinical services of the OBG department are delivered as Emergency services (24x7), Routine OPD services for general Obstetrics & Gynaecology health consultations, Family Planning counselling & services; Special Clinic services for specific focus areas such as High Risk Pregnancy, Gynaecologic Oncology, Infertility & Minimal Access Gynaecologic surgery, Adolescent Gynaecologic services, and Urogynaecology; IPD services in dedicated wards for Antenatal, Postnatal, Gynaecology, Obstetric HDU, and ICU; Operative services in Major OT, Emergency OT & Minor OT. In addition, the

department provides Telemedicine consultation services as part of tripartite collaboration with NHM-MP, average montly census Similarly the Jai Prakash district hospital of Bhopal is known as 1250 where most of the population of Bhopal outreaches to seek health care services .

The antenatal clients who utilize the ANC OPD services are from urban and rural areas of Bhopal, District. The record maintained in the antenatal OPD indicate that on an average, there are 5- 10 low risk primigravida women new cases being registered on any given antenatal OPD day, out of this 3 to 6 primigravida low risk women in between 35 weeks to 36 weeks + 6 days of period of gestation, befitting the criteria at the study samples.

The rationales behind doing the study in the selected hospitals were:

- Familiarity with the area
- Feasibility of conducting the study
- Convenience for researcher to assess the subject
- Administrative approval and cooperation for the study
- Availability of sample subjects in the selected areas of these setting

Population

Population refers to the entire population in which the researcher is interested and to which he or she would wish to make generalization of the study results.[68]

The term **Target population** refers to any definable group of individuals who are experiencing a problem or need.[70]

In this study target population were the Primigravida pregnant women between 35 weeks to 36 weeks + 6 days period of gestation with normal course of pregnancy visiting antenatal OPD of tertiary care hospitals.

The **accessible population** comprises the group of study participants who meet the specified criteria and are available for selection by the researcher.[70]

In present study is Primigravida pregnant women between 35 weeks to 36 weeks + 6 days period of gestation with normal course of pregnancy visiting antenatal OPD of selected tertiary care hospitals of Bhopal.

Sample

A sample is a subset of the defined population which is selected by the researcher as a participant of the research study. It represents the target population and is used to draw the inference about the population.[68]

In present study the sample were the Primigravida pregnant women between 35 weeks to 36 weeks + 6 days period of gestation with normal course of pregnancy attending and available in antenatal OPD of AIIMS Bhopal and Jai Prakash hospital Bhopal during the duration of data collection.

Sampling criteria

Sampling criteria are those essential traits of the respondents that must be met in order for them to be included in the study [68]. The key components of the current investigation are covered in the section below.

Inclusion criteria

The criteria that specify the characteristics that people in the population must possess are referred as inclusion criteria.

In this study inclusion criteria were:

Pregnant women who were

- Pregnant for the first time (Primigravida)
- Willing to participate in study
- Above the age of 18 years
- at, or crossed 35 weeks gestation but less than 37 weeks of gestation with normal course of pregnancy.
- Possessing a smart phone and know how to use it
- Can read and/ or write and/ or understand Hindi/English or both

Exclusion criteria

The study excluded the,

Pregnant women who were

- With any medical & surgical comorbidities which might complicate the pregnancy
- Taking any childbirth preparation classes
- Having any documented psychological disorder.

Sample size

It refers to the number of sample elements from which data is collected in order for evaluation of findings to be statistically significant, number of subject units in a sample make the sample size.[68]

Using power analysis (openepi statistical programme) and a minimum 80% power value and 5% threshold of significance, the sample size was determined. There was a minimum sample size of 47 participants each group.

The suggested sample size was 94 pregnant women **(**Annexure-3)

100 pregnant women with 50 in each interventional group and control group respectively.

Sampling technique

Sampling is a process of selecting a group of people events, behaviour or other elements that are representative to the population being studies.([68])

In this study the **non- probability convenient sampling** was used.

The convenient sampling technique is more practical and suitable for the researcher to use the most readily available or convenient group of pregnant mothers for the sample.

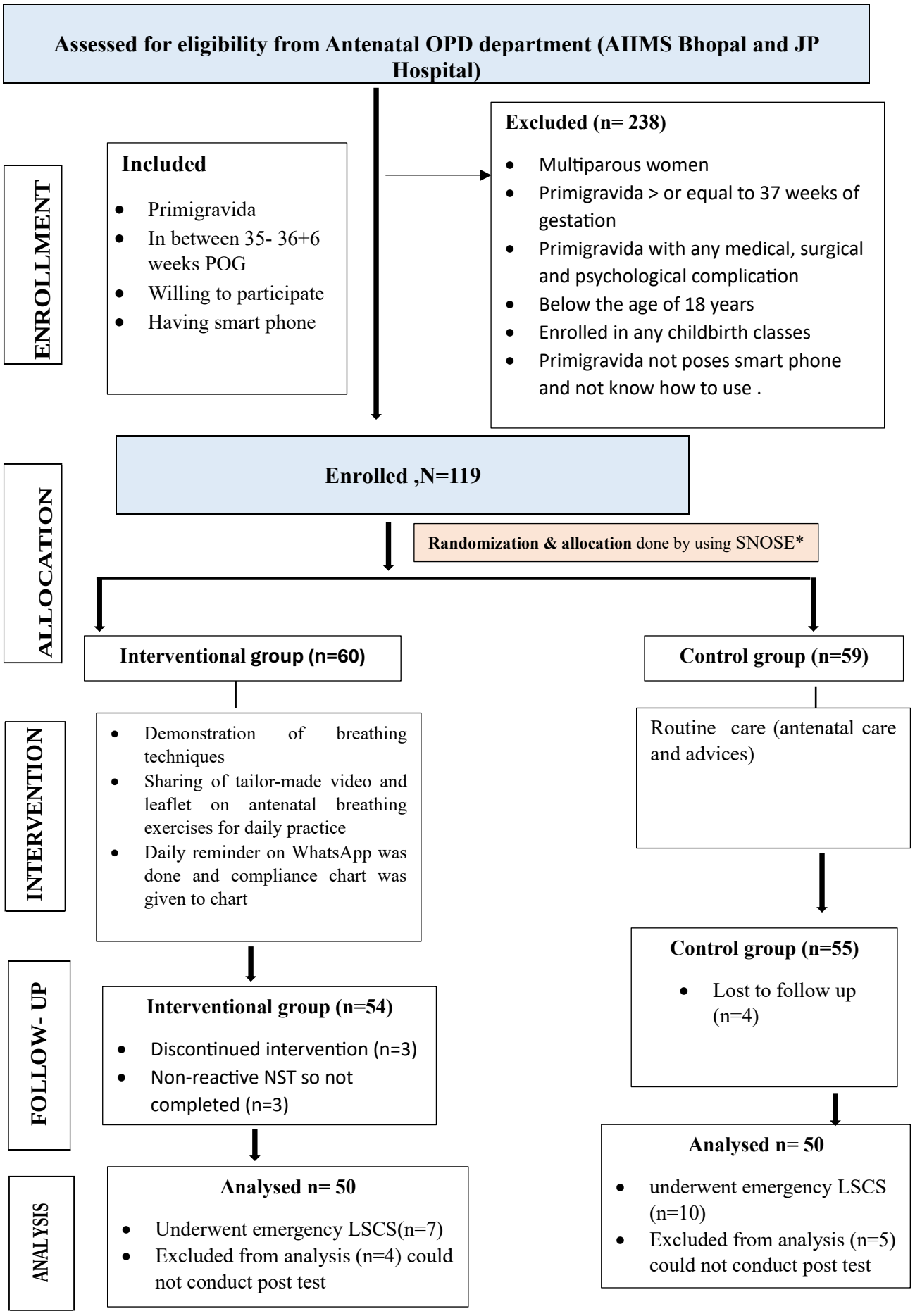

Assessed for eligibility from Antenatal OPD department (AIIMS Bhopal and JP Hospital)
ENROLLMENT
Included
Primigravida
In between 35- 36+6 weeks POG
Willing to participate
Having smart phone
Excluded (n= 238)
Multiparous women
Primigravida > or equal to 37 weeks of gestation
Primigravida with any medical, surgical and psychological complication
Below the age of 18 years
Enrolled in any childbirth classes
Primigravida not poses smart phone and not know how to use .
ALLOCATION
Enrolled ,N=119
Randomization & allocation done by using SNOSE*
Interventional group (n=60)
Control group (n=59)
INTERVENTION
Demonstration of breathing techniques
Sharing of tailor-made video and leaflet on antenatal breathing exercises for daily practice
Daily reminder on WhatsApp was done and compliance chart was given to chart
Routine care (antenatal care and advices)
FOLLOW- UP
Interventional group (n=54)
Discontinued intervention (n=3)
Non-reactive NST so not completed (n=3)
Control group (n=55)
Lost to follow up (n=4)
ANALYSIS
Analysed n= 50
Underwent emergency LSCS(n=7)
Excluded from analysis (n=4) could not conduct post test
Analysed n= 50
underwent emergency LSCS (n=10)
Excluded from analysis (n=5) could not conduct post test

Figure 9- CONSORT Flow chart of the participants

Data collection tools/ instrument

Development of the instruments

The research instruments used to gather the relevant data for the study are called data collecting instruments. These tools make it easier to collect data using arbitrary techniques like measurement and observation.[68]

Following steps were incorporated in development of research instruments.

Description scoring and interpretation of the Instrument tool

The preparation of the instruments for suitable data collection was directed by the study's objective. The instruments were divided into two major groups. (tools enclosed in appendices)

Section A: Screening

I. Screening Sheet

Section B: Data collection

I. Socio- Demographic variable Performa-

II. Clinical variable Performa

III. Labor outcome Sheet

IV. Childbirth experience questionnaire

Section A: Screening

Screening Sheet (Annexure – 4 and 5)

This tool was developed considering the inclusion and exclusion criteria of the study. Primary screening of 357 Pregnant women attending the antenatal OPD was looking into the criteria. Around 238 pregnant women were excluded from participation in the study as they were not meeting the inclusion criteria.

Section B: Data collection

I. Demographic variable Performa (Annexure- 4 and 5)

Comprised of nine items on personal data such as age, education, occupation, residence, religion, type of family, social support, smoking habit, pregnancy planned.

II. Clinical variable Performa (Annexure-4)

Compromised of items related to clinical data like LMP, EDD, POG, any past medical and surgical history, any medical disorder happen during pregnancy, clinical details of subsequent visit.

III. Labor outcome Sheet (Annexure-4)

A structured labor outcome sheet was prepared by the investigator to assess the labor outcome. For the selection of items and preparation of tool a review of research and non-research literature was done in the area. Opinion of experts was sought to ascertain the appropriateness of these items.

the labor outcome sheet consisted of two parts

Part A- of the labor outcome sheet consisted of 9 areas regarding maternal outcome.

The areas are as follows

1. Onset of labor
2. Nature of progress of labor
3. Mode of delivery
4. Nature of vaginal delivery
5. Nature of expulsion of placenta
6. Total duration of labor
7. Duration of each stage of labor
8. Any sign of PPH

Part B- of the labor outcome sheet comprised of 4 areas regarding fetal outcome

The areas are as follows:

1. The birth of newborn whether alive, or dead or asphyxiated
2. APGAR score at 1 minute after birth
3. APGAR score at 5 minutes after birth
4. Presence of any birth complication

Part C- Childbirth experience questionnaire (CEQ) (Annexure-4 and 5)

To measure the important aspect of Maternal outcome, that was childbirth experience, to collect relevant data, d developed the tool Childbirth Experience Questionnaire by taking reference from child birth experience questionnaire(73) . It is a self-assessment scale aimed at evaluating the quality of a women's subjective childbirth experience and overall satisfaction with childbirth. It consist of 17 items. The response format of the first 14 statement is a four- point Likert scale ranging from 1 to 4, 1 (totally disagree); 2 (mostly disagree); 3 (mostly agree); and4 (totally agree). Questions no. 15, 16 and 17 are assessed using a visual analogue scale (VAS) ranging from 0 to 100 points; the scores from the VAS are then converted as follows:

0-40 points = 1 points;41-60 points = 2 points; 61- 80 points = 3 points and81-100 points = 4 points.

Question no. 3, 5, 8, and 15 was reversed scored.

Using this scale, women expressed the degree of pain, control over childbirth, how safe they felt during childbirth, and their degree of control during childbirth.

Minimum score: 17

Maximum score: 68 (Table no. 1)

Table no. 1

Categories of childbirth experience questionnaire score

Childbirth experience questionnaire	Categories	Scores
	Positive	51-68
	Neutral	34-50
	Negative	17-33

Table no. 2

Summary of data collection tools and technique

TOOL	Purpose	Data collection technique
1. Demographic variable Performa **2.** Clinical variable Performa	To collect background data To collect history of present pregnancy	By interview technique
3. Labor outcome a) Maternal outcome sheet b) Fetal outcome sheet c) Childbirth experience questionnaire	• To collect data regarding maternal outcome in terms of POG at onset of labor, Onset of labor, Nature of progress of labor, Mode of delivery, Nature of vaginal delivery, Nature of expulsion of placenta , Total duration of labor, Duration of each stage of labor, Any sign of PPH	Direct observation

	• To collect data regarding neonatal outcome like birth of newborn whether alive, or dead or asphyxiated, APGAR score at 1 minute after birth , APGAR score at 5 minutes after birth, Presence of any complication/ birth injury	Direct observation
	• To collect information regarding mother experience of childbirth	Interview technique

Validity and Reliability of the tool

Validity of the tool: validity is the degree of measurement of an instrument that is supposed to be measure. It refers to appropriateness of the instrument. (68)

Content Validity concerns the degree to which an instrument has an appropriate number of items for the construct being measured and adequately covers the construct domain (68)

The process of tool validity was done under guidance of guide and co guide in following steps; firstly, draft of the tool was prepared after reviewing the literature. In second step letter requisition for opinion of experts on validity of tool and validity certificate was prepared. In third step list of experts (Annexure-6), letter for validation of tool (Annexure- 7), criteria checklist for the validation of tool (Annexure-8), content

validation certificate (Annexure-9) was prepared and approached them by contacting through email and face to face.

The tool was sent to total 23 experts, in areas of Obstetrics and gynaecology (4) obstetrics and gynaecology nursing (8), Physiotherapist working in maternal and child health (8) and yoga instructor working in maternal area (3), out of 23 experts 11 validated and returned the tool. Final tool contained total 8 questions in screening sheet, 9 questions in Socio-demographic variable Performa , 5 items in clinical variable Performa, 13 items in labor outcome sheet and 17 questions in childbirth Experience questionnaire.

Based on the validator's suggestions, modifications were incorporated and tool was finalized in the consultation with guide and co-guide. Scale content validity index and content validity index (CVI) was calculated. (Table no. 3). Subsequently all the tools were translated in Hindi and retranslated back into English. Finally, they were validated by subject matter and language experts, back translation version of English tool was compared with the original English tool and was found to have a semantic equivalence. (Annexure-10)

Table no. 3

Validity of tools

s.no.	Tool Name	S-CVI	Interpretation
1.	Screening Tool	0.97	Acceptable
2.	Socio-Demographic Performa	0.89	Acceptable
3.	Clinical variable Performa	0.91	Acceptable
4.	Labor outcome sheet	0.94	Acceptable

5.	Childbirth experience questionnaire	0.86	Acceptable

Reliability of the tool: Reliability refers to the consistency and accuracy of an instrument with which it measures the target attribute for the purpose it is designed.(68)

To establish reliability the tools were administered to 5 pregnant women.

This tool's dependability was assessed using the inter-rater reliability approach. The degree to which the study's data accurately reflect the variables being measured is indicated by the inter-rater reliability. Inter rater reliability is the measurement of the degree to which data collectors (raters) give the same score to the same variable. An estimate of the test standardisation and raters' proficiency in applying scoring criteria accurately are provided by inter-rater reliability (38). In order to ensure objectivity, the tool's consistency was verified by having two observers administer it separately to five pregnant women on the same day. The investigator gave the observers training so they could use the tool to watch the incident. The primary rater was one observer, and the other one was secondary rater and data were compared.

Table no. 4

Reliability of tool

Sl.no.	Tool	Kappa value
1.	**Labor outcome sheet**	
	a) Maternal outcome sheet	0.91
	b) Fetal outcome sheet	0.91
	c) Childbirth experience questionnaire	0.87

Above are the values of the respective tool, and were inferred to be reliable in data collection.

Description of the intervention

The aim of the researcher in the current study was to improve labor outcome among pregnant women with the help of nurse led breathing exercise intervention Protocol.

Nurse- led breathing exercise intervention protocol was exclusively, methodically crafted for the Primigravida Pregnant women. Designed by the researcher, a multipronged Protocol.

Nurse- led breathing exercise intervention protocol consist of four components

1. Tailor made video on antenatal Breathing Exercise
2. Physical demonstration and re-demonstration by Participant of breathing exercise intervention protocol
3. Information leaflet on antenatal breathing exercise.
4. Compliance chart and WhatsApp group for compliance

During the initial meeting (35–36+6 weeks of gestation), a PIS was administered and informed permission was acquired. Data on demographic and clinical conditions were gathered. The women in the intervention group watched a specially produced nine-minute film on antenatal breathing exercises, had given instruction, and were instructed to practise the exercises twice a day, every day, even as their labour progressed.

Credentials of Researcher

Certified antenatal postnatal exercise specialist (CAPES) from international health and fitness association, India (Annexure-11)

1. **1st interaction with interventional group mother (POG between 35 weeks to 36+6 days)**

Tailor made video on antenatal Breathing Exercise

Preparation and validation of tailor-made video:

The content of the video was prepared after review of similar studies. The topics included in the video content (annexure-12) are: Brief introduction about labor and child birth , importance and advantages of breathing exercise during labor, and recorded demonstration of set of breathing exercises .

The content of video was validated by five experts from the field of Obstetrics and gynaecology and Physiotherapist (Annexure-13). Informed consent was obtained from individual who enacted the role of pregnant women (Annexure-15) .The video was prepared and send for validation to the same subject experts who validated the content of video. The suggestion of experts was incorporated after discussing with guide and co-guide. The final video was prepared in Hindi language of duration 8 and minutes 48 seconds. The video was also pretested among 9 pregnant women. The women expressed the language (spoken and written) and the video were clear. Technical validity of video was established with the video editing expert and clarity and quality of video was ensured. (Annexure-14)

Physical demonstration of breathing exercise by the researcher following which participant will be asked to redemonstrate it

Demonstration includes:

Instruction before starting set of breathing exercise

Before start any breathing exercise find a comfortable position to perform

• Wear comfortable, loose clothing when doing the exercises

• Do the exercise twice a day , 2 sets of breathing exercise protocol each time (morning just after the wake up and night before going to sleep)

• Do not exercise immediately after eating; keep a gap of atleast ½ hour.

• Relax your body – close your eyes if you're comfortable doing so.

• Loosen any tight clothing that might restrict your breathing

• Place your one hand on your chest and other on your belly. One set consist of

i. **Deep cleansing breath** – Perform for 30 second

How to perform- inhale slowly and deeply ,then hold your breath and exhale slowly and completely.

set a count ,inhale count of a four ,hold for a count of four and exhale for a count of six , adjust the count what feels comfortable for you .

ii. **Slow paced breathing** – Perform for next 30 second

How to perform: inhale through your nose on count of four and exhale through your mouth on count of six ,exhale like you were trying to flicker the flame of a burning candle held at arm length or feather held at arm length would barely move on the outward breath.

iii. **Light and more rapid breath** /modified paced breathing- perform for next 30 second

How to perform- The rhythm for the breath counted as 1,2,1,2,1,…. with the women exhaling on 1 and inhaling on 2.

iv. **Pant blow breath**-perform for next 30 second

How to perform: during exhale accompanied by a sound ,you can perform either by 3:1, 2:1. For ex. Hee,hee,hoo (quick inhale on hee and quick exhale on hoo.)

Deep cleansing breath- end one set with deep cleansing breath.

Information leaflet on antenatal breathing exercise

The content of the information leaflet was prepared after review of similar studies. The topics included in the leaflet content are: instruction before performing beathing exercises, set of breathing exercise consist of and short description of how top perform each breathing exercise. All the images included in leaflet was prepared by the researcher. (Annexure-16)

The content of leaflet was validated by five experts from the field of Obstetrics and gynaecology and Physiotherapist. Subsequently information leaflet was translated in Hindi and retranslated back into English. Finally, that was validated by subject matter and language experts, back translation version of English information leaflet was compared with the original English leaflet and was found to have a semantic equivalence. (Annexure-10)

Compliance chart and WhatsApp group for compliance

For charting breathing exercise which will be performed by the participants two times daily and followed up during subsequent weekly visits. (Annexure-17)

WhatsApp was created to send voice reminder twice daily for performing breathing exercise and to do biweekly individual or group video call as per convivence to assess the compliance and accuracy.

2. <u>Subsequent interaction with interventional group during each antenatal visit (from recruitment till onset of labor)</u>

During weekly antenatal visit reemphasize on regular practice of breathing exercise instructed and checking of compliance checklist.

During the last visit also demonstrated the pushing breath

Pushing Breath-

How to perform:

Either lie down using 2 pillows under your head or sit with your back supported by wall and your legs stretched in front of you.

Perform one slow paced breathing (inhale through nose up to your waist and blow out through pursed lip)

2nd slow paced breath

3rd slow paced breath , after inhaling hold your breath .while holding your breath incline your chin slightly towards you chest.

Then followed by relaxing breath

3. During different stages of labor

Interventional group participants was encouraged to perform breathing exercise according to their stages of labor and contraction by the researcher.

Table no.5

Breathing exercise according to different stage of labor

Type of breathing	When to perform
Deep cleansing breath	in between the contraction
Slow paced breathing	During early stage of labor
Light and more rapid breath /modified paced breathing	more strong contraction (when cervical dilatation 5 to 8 cm)
Pant blow breath	Transition phase and also 2nd stage contraction
Pushing breath	During pushing in 2nd stage of labor
Relaxation breath/ cleansing breath	During 3rd stage of labor

Group			Post test	
Participant	1st interaction (35 weeks to 36+6 POG)	During each subsequent visit	At the time of labor	within 24-48 hours of delivery
Interventional Group	Recruitment and tailor-made video , demonstration, compliance chart and WhatsApp group	Follow up, assess compliance by compliance chart and taught pushing breath during last visit	Encouraged to perform breathing exercise and record labor outcome in maternal and neonatal outcome sheet	Collect data regarding Childbirth experience by interview
Control Group	Recruitment	NO INTERVENTION	Record labor outcome in maternal and neonatal outcome sheet	Collect data regarding Childbirth experience by interview

Figure 10: Schematic representation of the intervention protocol

Ethical Consideration

Following are the minutiae of the ethical deliberation covered while conducting the study, All the ethical clearance were obtained prior to the commencement of data collection and are listed below

Ethical Clearance

Ethical clearance for the study was taken from the Institutional Human Ethics Committee-Student Research (IHEC-SR) AIIMS Bhopal (Ref number: AIIMS/BPL/IHECSR/July/22/MscN/22)

Administrative Permission

Permission was obtained from Medical Superintendent, head of the department (Obstetrics and Gynaecology) and Assistant nursing superintendent of labor room and OPD of AIIMS Bhopal to conduct the research.(Annexure-1)

Permission was also obtained from Civil Surgeon and Community medical officer of Jai Prakash district hospital, Bhopal to conduct the study. (Annexure-2)

Trial registration

The current investigation was filed with the Clinical Trial Registry of India (CTRI/2023/09/057601), an official database that permits data collection for health interventions to be safe and effective while also offering greater access and transparency to clinical studies.

Informed Consent

Prior to their enrollment in the trial, every pregnant woman received a written subject information sheet that included an explanation of the study's specifics. The participants were informed of the benefits and harms (none) of their involvement as well as who to contact in the event of any questions. The study participants' confidentiality was protected. Also, study participants gave their informed consent. (Annexure 18,19 and 20)

Pilot study

Pilot study is the small trial run of the methodology planned for actual study. The purpose of the pilot study is twofold: to make improvement in the research project and to detect any problem that must be eradicated before the major study is attempted. [69]

Pilot study was conducted in September 2023 (7/9/23 to 22/9/23) in antenatal OPD and labor room of AIIMS Bhopal. Prior to the data collection, written permission was sought from the administrative head of the AIIMS Bhopal. Total 23 pregnant women were screened, out of which 10 pregnant women enrolled in the pilot study (5 in each group interventional and control group).

It was concluded, as feasible to conduct the study in terms of application of tools and nurse-led breathing exercise intervention protocol.

Procedure of data collection

The main study data was collected between 25th September 2023 to 9/12/23 in antenatal OPD and labor room of AIIMS Bhopal and Jai Prakash district hospital, Bhopal. In this study the data collection procedure is depicted in table no. 6

Table no. 6

Data Collection Procedure

Step 1- Obtained administrative approval

Step 2- screening using inclusion and exclusion criteria (screening tool appendices)

Step 3- full disclosure regarding the study (provide PIS) (Appendices)

Step 4- Informed consent was taken from the pregnant women (Appendices-)

Step 5- Pregnant women randomly using SNOSE* divided into two

Interventional group			**Control group**		
Weeks	**Status of the participants**	**Activities**	**Weeks**	**Status of the participants**	**Activities**
1st interaction with interventional group mother	Primigravida pregnant with POG between 35 weeks to 36+6 days	Tailor made video Shown ,demonstration, compliance chart and WhatsApp group created and add participant into that.	1st interaction with interventional group mother	Primigravida pregnant with POG between 35 weeks to 36+6 days	Routine care (antenatal care and health education)
During each subsequent visit		Follow up, assess compliance by compliance chart and taught pushing breath during last visit	During each subsequent visit		No intervention
At the time of labor when participant came	At different stages of labor	Encouraged to perform breathing exercise and record labor outcome	At the time of labor when participant came	At different stages of labor	Record labor outcome
Within 24-48 hours of delivery	Postnatal day 0 - 2	Childbirth experience assessed	Within 24-48 hours of delivery	Postnatal day 0- 2	Childbirth experience assessed

***** Sequentially numbered opaque sealed envelope

Plan for data analysis

Data analysis is a process used to reduce, organize and give meaning to the data for answering research question and testing hypothesis.(68)

According to objective and hypothesis of the study and opinion of the experts it was planned to organize and tabulate, analyse and interpret the data by using both descriptive and inferential statistics. The following plans of analysis were developed table no. 7 plan of data analysis

Table no.7

Plan of data analysis

Sl. No	Objective	Measures	Statistical test	Statistical software
1.	To assess the effect of nurse led breathing exercise intervention protocol on labor outcomes in terms of maternal and neonatal outcome among pregnant women	**Maternal Outcome** • POG at onset of true labor • Onset of labor • Nature of progress of labor • Mode of delivery • Nature of vaginal delivery • Nature of expulsion of placenta • Total duration of labor • Duration of each stage • Any sign of	**Descriptive** ✓ Frequency ✓ Percentage ✓ Mean ✓ Standard deviation **Inferential** ✓ Test of normality ✓ Man-Whitney U test ✓ Linear regression	SPSS 26 and jamovi 2.4

		PPH **Neonatal outcome** • The newborn born • APGAR At 1 min • APGAR at 5 min • Any birth injury		
	To associate labor outcome with selected demographic variables among pregnant women	• Demographic variable • Maternal outcome • Neonatal outcome	Chi square/ Fisher Exact test	SPSS 26

SUMMARY

This chapter dealt with methodology adopted for the present study . It includes the Research Methodology , the Research Approach, the Research Design, Variables of the study setting , Sample and Sampling technique , Data collection tool , Development and description of tool , Content Validity & Reliability of tool ,Pilot study ,Procedure for data collection & Plan for data analysis. The next chapter will be dealing with analysis and interpretation of the finding of the study.

CHAPTER- IV

RESULT

Introduction

This chapter deals with the analysis and interpretation of data collected to evaluate the effectiveness of nurse-led breathing exercise intervention protocol on labor outcome among pregnant women.

The data was collected from 100 Pregnant women i.e. 50 in interventional group and 50 in control group, through structured socio-demographic tool, labor outcome sheet and childbirth experience questionnaire. The raw data was entered into excel sheets, was analysed, classified and presented in tabulated or graph as per the objectives and hypothesis of the study. Quantitative data was analysed by using SPSS 26.0 version software and jamovi (version 2.4)

All data were tabulated and summarized in the master data sheets.

Polit and Hunger (1999)(38) stated that data analysis is the systematic organization and synthesis of research data, and the testing of research hypothesis using those data.

According to Abdellah and Levine (1979)(39) interpretation of tabulated data can bring to light the real meaning of the finding of the study.

Objectives

1. To develop and administer nurse led breathing exercise intervention protocol to the Interventional group.
2. To assess the effect of nurse led breathing exercise intervention protocol on labor outcomes in terms of maternal and neonatal outcome among pregnant women.

3. To find association between labor outcome with selected demographic variables among pregnant women.

Hypothesis

1. **H01:** There is no difference in maternal outcome among pregnant women of interventional group after the administration of Nurse led breathing exercise intervention protocol at 0.05 level of significance as measured by maternal outcome sheet and childbirth experience questionnaire.
2. **H1:** There is significant difference in maternal outcome among pregnant women of interventional group after the administration of Nurse led breathing exercise intervention protocol at 0.05 level of significance as measured by maternal outcome sheet and childbirth experience questionnaire.
3. **H03:** There is no significant association between selected demographic variables and maternal outcome at 0.05 level of significance
4. **H02:** There is no difference in neonatal outcome among pregnant women of interventional group after the administration of Nurse led breathing exercise intervention protocol at 0.05 level of significance as measured by neonatal outcome sheet .
5. **H3:** There is significant difference in neonatal outcome among pregnant women of interventional group after the administration of Nurse led breathing exercise intervention protocol at 0.05 level of significance as measured by neonatal outcome sheet .
6. **H04:** There is no significant association between selected demographic variables and neonatal outcome at 0.05 level of significance

According to Best (1992)[74] "a null hypothesis is concerned the judgment as to whether, apparent difference with relationships, are true difference or relationship or whether they merely results from a sampling error."

Best also added that "the rejection or acceptance of a null hypothesis is based on some level of significance as a criterion. To psychology and education, 0.05 level of significance is often used as a standard for rejecting or accepting a hypothesis"

So, the level for accepting or rejecting a hypothesis was set at 0.05 level.

Polit and Hungler (1999)([38]) stated that "the null hypothesis is a statement that there is no actual relationship between variables and that any such observed relationship is only a function of chance, or sampling fluctuations. The need for null hypothesis lies in the fact that statistical hypothesis testing is basically a process of rejection. It is possible to show that the null hypothesis has a high probability of being incorrect, and such evidence lends support to the scientific hypothesis. The rejection of null hypothesis, then, is what the researcher seeks to accomplish through statistical tests."

Organization and Presentation of data

The obtained data were analysed, tabulated and interpreted by employing descriptive and inferential statistics. The data have been organized under following section.

Section 1 Finding related to description of the samples (Pregnant women) according to their demographic characteristics

1.1 Finding related to sample characteristics of pregnant women in interventional and control group in terms of their demographic variables.

1.2 Finding related to sample characteristics of pregnant women in intervention and control group in terms of age, POG at enrolment and POG at onset of labor.

Section 2 Findings related to the assessment of labor outcomes in the intervention and control group in terms of maternal and neonatal outcomes.

2.1 Findings related to the assessment of labor outcomes in the intervention and control group in terms of maternal outcomes.

2.1.1 Assessment of onset of labor, nature of progress of labor, mode of delivery among pregnant women in interventional and control group

2.1.2 Assessment of nature of vaginal delivery, expulsion of placenta, sign of PPH among pregnant women who underwent Vaginal delivery in interventional and control group.

2.1.3 Assessment of total duration, duration of each stage of labor and drop rate of oxytocin among pregnant women who underwent vaginal delivery in interventional and control group.

2.1.4 Assessment of Childbirth Experience among pregnant women in interventional and control group.

2.2 **Findings related to the assessment of neonatal outcomes in the intervention and control group.**

Section 3 Finding related to effectiveness of nurse led breathing exercise intervention protocol on labor outcome among pregnant women in intervention and control group

3.1 Finding related to effectiveness of nurse led breathing exercise intervention protocol on Maternal outcome among pregnant women in interventional and control group

3.1.1 Effectiveness of nurse led breathing exercise protocol on onset of labor, nature of progress of labor, mode of delivery among pregnant women in interventional and control group

3.1.2 Effectiveness of nurse led breathing exercise protocol on nature of vaginal delivery, expulsion of placenta, sign of PPH among pregnant women who underwent Vaginal delivery in interventional and control group.

3.1.3 Effectiveness of nurse led breathing exercise protocol on total duration and duration of each stage of labor among pregnant women who underwent Vaginal delivery in interventional and control group.

3.1.4 Effectiveness of nurse led breathing exercise protocol on Childbirth Experience among pregnant women in interventional and control group.

3.1.5 Linear regression analysis of the effectiveness of nurse led breathing exercise intervention protocol on childbirth experience controlling for other independent variables in interventional and control group.

3.2 Finding related to effectiveness of nurse led breathing exercise intervention protocol on neonatal outcome in interventional and control group

Section 4 Finding related to association of the labor outcome with selected demographic variables

3.1 Association between maternal outcome with selected demographic variable

3.2 Association between neonatal outcome with selected demographic variables.

Section- 1

Finding related to description of the samples (Pregnant women) according to their demographic characteristics

This section describes the demographic characteristics of subjects, which provide background information.

There are two subsections in this section:

1.1 Finding related to sample characteristics of pregnant women in interventional and control group in terms of their demographic variables.

The data is being presented in table 8

1.2 Finding related to sample characteristics of pregnant women in intervention and control group in terms of age, POG at enrolment and POG at onset of labor.

The data is being presented in table 9

1.1 Finding related to sample characteristics of pregnant women in interventional and control group in terms of their demographic variables.

The data was collected from 100 pregnant women (50 from intervention and 50 from control group) ,Frequency and percentage distribution of the sample are given in table no. 8.

Table no. 8

Frequency, percentage and homogeneity comparison of demographic characteristics of pregnant women in intervention and control group.

N=100

Characteristics	**Categories**	Intervention **group (n=50)**		**Control Group (n=50)**		**p-value**
		Frequency	**Percentage**	**Frequency**	**Percentage**	
Education	Professional	8	16.0	7	14.0	0.685
	Graduate	12	24.0	**16**	**32.0**	
	Intermediate or diploma	10	20.0	12	24.0	
	High school certificate	**13**	**26.0**	11	22.0	
	Middle school certificate	5	10.0	4	8.0	
	Primary school certificate	2	4.0	0	0.0	
	Illiterate	0	0.0	0	0.0	
Occupation	Home maker	**35**	**70.0**	**35**	**70.0**	0.865
	Professional	7	14.0	8	16.0	
	Self-employed	7	14.0	5	10.0	
	Work from home	1	2.0	2	4.0	
Residence¥	Rural	23	46.0	24	48.0	1.000
	Urban	**27**	**54.0**	**26**	**52.0**	
Religion	Hinduism	**43**	**86.0**	**38**	**76.0**	0.426
	Christianity	3	6.0	6	12.0	
	Islam	4	8.0	6	12.0	
	Others	0	0.0	0	0.0	

Type of family	Nuclear	**26**	**52.0**	**32**	**64.0**	0.600
	Joint	24	48.0	18	36.0	
Social support	Husband	14	28.0	14	28.0	0.396
	Parents	15	30.0	**20**	**40.0**	
	In-laws	**19**	**38.0**	16	32.0	
	Relative	2	4.0	0	0.0	
	Any other	0	0.0	0	0.0	
Smoking habit	Yes	0	0.0	0	0.0	--
	No	**50**	**100.0**	**50**	**100.0**	
Pregnancy planned¥	Yes	8	16.0	15	30.0	0.153
	No	**42**	**84.0**	**35**	**70.0**	

Chi-square test; ¥Fisher exact test, N= total no. of samples

The data depicted in table 8 shows that 13 (26%) of samples in interventional group were educated up to high school certificate and 16 (32%) samples in control group were educated up to graduate, maximum of the samples 35(70%) in both the group were housewife, Majority of the women from both the groups intervention 43 (86%) and control group 38 (76%) belonged to Hindu religion, lived in nuclear family interventional group 26 (52%) and control group 32 (64%). In terms of social support for majority of pregnant women of intervention group 19(38%) have in laws and in control group 20(40%) have parents, none of the participant have smoking habit and majority of women have present pregnancy is unplanned 42 (84%) in interventional group and 35(70%) in control group

To determine whether the groups were similar in their baseline characteristics chi- square test for categorical variables was carried out and p values were computed at .05 level of significance. As the calculated p values were greater than .05 level of significance in terms of demographic characteristics which indicates intervention and control groups were homogenous in all demographic characteristics at the time of recruitment to the study.

1.2 Finding related to sample characteristics of pregnant women in intervention and control group in terms of age, POG at enrolment and POG at onset of labor.

The data was collected from 100 pregnant women (50 from intervention and 50 from control group) ,mean and standard deviation of the age, POG at enrolment and POG at onset of labor are given in table no. 9.

Table no. 9

Mean, Standard Deviation and Homogeneity Comparison of age, POG at enrolment and POG at onset of labor of Pregnant Women in Intervention and control Group

N=100

Variable	Experimental (n=50)		Control (n=50)		p-value
	Mean	SD	Mean	SD	
Age in years	24.88	3.91	23.64	3.16	0.146
Period of gestation at enrolment (in weeks)	36.04	0.58	35.94	0.59	0.443
Period of gestation at onset of labor (in weeks)	39.43	0.87	39.36	0.96	0.926

N= total no. of samples, SD= standard deviation

The table 9 present Demographic characteristic of continuous variable (age, POG at enrolment and POG at onset of labor) of 100 pregnant women. Among 100 women, the mean age of women in the intervention group was 24.88 (SD ±3.91) years, and that of control group was 23.64 (SD±3.16) years. The mean period of gestation at which pregnant women were recruited/ enrolled for the study in the intervention group was 36.04 (SD±0.58) weeks, and that of control group was 35.94 (SD±0.443) weeks.

One way ANOVA was used to test whether the groups were similar in their baseline characteristics during recruitment, p values obtained were greater than .05 level of significance which indicates intervention and standard care groups were homogenous in terms of age, POG at enrolment and onset of labor at the time of recruitment to the study.

Section-2

Findings related to the assessment of labor outcomes in the intervention and control group in terms of maternal and neonatal outcomes

This section describes the assessment finding of labor outcome in terms of maternal and neonatal outcomes of the intervention and control group among pregnant women. All labor outcome was assessed during labor except childbirth experience which was assessed after delivery. Labor outcome was measured by structured Performa and questionnaire.

This section is divided into two subsections, with further subsections within each:

2.2 Findings related to the assessment of maternal outcomes in the intervention group and control group.

The data is presented in Tables No. 10, 11, 12, 13, 14, and 15, as well as Figures No. 9, 10, and 11.

2.3 Findings related to the assessment of neonatal outcomes in the interventional and control group

The data is being presented in table 16

2.1 Findings related to the assessment of maternal outcomes in the intervention and control group

2.1.1 Assessment of onset of labor, nature of progress of labor, mode of delivery among pregnant women in interventional and control group

Table no. 10

Assessment of onset of labor, nature of progress of labor, mode of delivery among pregnant women in interventional and control group by frequency and percentage

N=100

Maternal outcome	Categories	Interventional group(n=50)		control group(n=50)	
		f	%	f	%
Onset of labor	**Spontaneous**	**38**	76.0	**32**	64.0
	Induced	12	24.0	18	36.0
Nature of progress of labor	**Progressed spontaneously**	0	0.0	1	2.0
	Augmented	**50**	100.0	**49**	98.0
Mode of delivery	**Vaginal delivery**	**42**	84.0	**36**	72.0
	Instrumental delivery	1	2.0	4	8.0
	Emergency LSCS	7	14.0	10	20.0

N= total no. of samples, f= frequency, % Percentage

According to the data in table 10, 38 38 (76%) of the pregnant women in the interventional group and 32 (64%) of the control group went into spontaneous onset of labor and nearly all of these women's labor were augmented 50 (100%) of them in the intervention group and 49 (98%) in control group.

The highest percentage of the sample 42 (84%) in the interventional group and 36 (72%) in the control group underwent vaginal delivery.

N=100

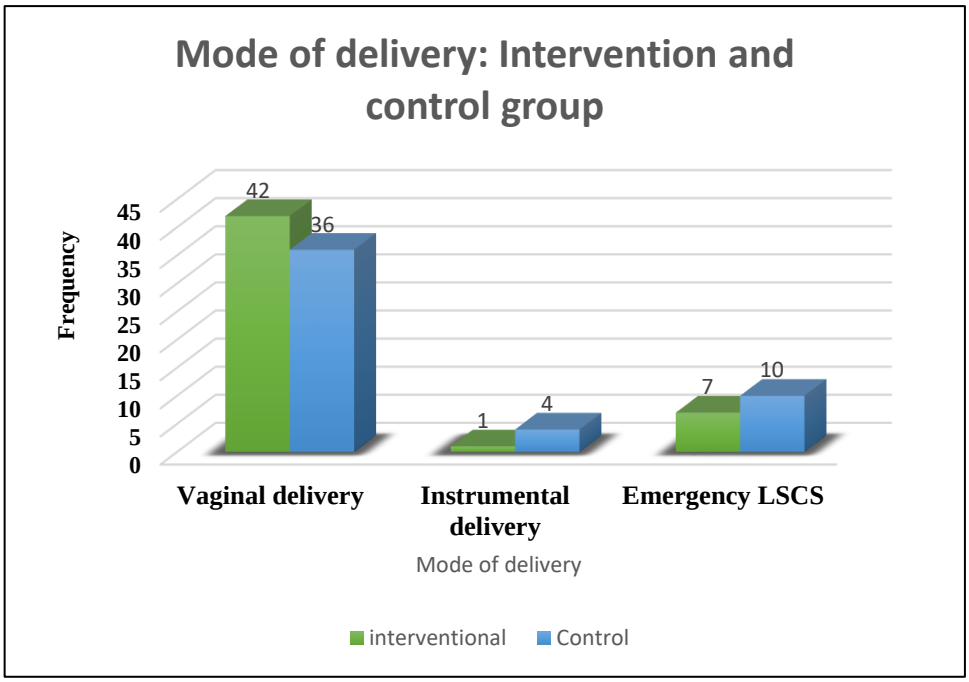


Figure 11: Bar Diagram showing the frequency distribution of pregnant women according to the mode of delivery in interventional and control group

Above depicted that among 50 pregnant women, 42 in interventional group and 36 in control group underwent vaginal delivery, followed by 7 in interventional group and 10 in control group underwent emergency LSCS.

2.1.2 **Assessment of nature of vaginal delivery, expulsion of placenta, sign of PPH among pregnant women who underwent Vaginal delivery in interventional and control group.**

Table no. 11

Assessment of nature of vaginal delivery, expulsion of placenta, sign of PPH among pregnant women who underwent Vaginal delivery in interventional group and control group by frequency and percentage

N=83

Maternal outcome	Categories	Interventional		Control	
		f (n=43)	%	f (n=40)	%
Nature of vaginal delivery	**VD with episiotomy without laceration and tear**	**28**	65	**22**	55
	VD with episiotomy and laceration	4	9	5	12
	VD with episiotomy and tear	5	12	9	23
	VD without episiotomy	6	14	4	10
Nature expulsion of placenta	**Spontaneous**	**39**	91	**33**	83
	Assisted	4	9	6	15
	Manual removal	0	0	1	3
Any sign of PPH	**Yes**	0	0	3	8
	No	**43**	0	**37**	93

N= total no. of samples, f= frequency, % Percentage

The data presented in Table 11 indicates that the majority of the sample, comprising 28 participants (65%) in the interventional group and 22 participants (55%) in the control group, delivered vaginally with episiotomy but without laceration or tearing. Additionally, 39 participants (91%) in the interventional group and 33 participants (83%) in the control group delivered the placenta spontaneously. None of the participants in the interventional group exhibited any signs of postpartum haemorrhage (PPH), whereas in the control group, 37 participants (93%) did not show any signs of PPH.

2.1.3 Assessment of total duration, duration of each stage of labor and drop rate of oxytocin among pregnant women who underwent vaginal delivery in interventional and control group.

Table no. 12

Mean and SD of duration of each stage of labor and drop rate of oxytocin among pregnant women who underwent vaginal delivery in interventional and control group.

N=83

Variable	Interventional (n=43)		Control (n=40)	
	Mean	SD	Mean	SD
Oxytocin drop rate	32.00	18.85	50.05	15.86
Duration of 1st stage (in hrs)	5.42	0.64	6.02	0.72
Duration of 2nd stage (in mins)	38.86	12.90	90.23	41.61
Duration of 3rd stage (in mins)	6.79	3.26	9.20	5.13

N= total no. of samples, SD= standard deviation, hrs- hours, min- minutes

Table above represented the mean and SD of oxytocin drop rate, duration of 1st stage, 2nd stage and 3rd stage of labor in interventional and control group, for oxytocin drop rate in interventional group mean was 32.00 (SD±18.85) and 50.05 (SD±15.86), for control group respectively, for duration of 1st stage of labor mean duration of labor 5.42 hours (SD±0.64) in interventional group, 6.02 hours (SD±0.72) in control group.

Table no. 13

Mean and SD of total duration labor among pregnant women who underwent vaginal delivery in interventional and control group.

N=83

Group	Mean (In hours)	SD
Interventional group (n=43)	6.20	0.63
Control group (n=40)	7.71	0.94

N= total no. of samples, SD= standard deviation, hrs- hours

The data presented in Table 13 indicates that the mean total duration of labor for the interventional group was 6.20 hours, while it was 7.71 hours for the control group.

N=83

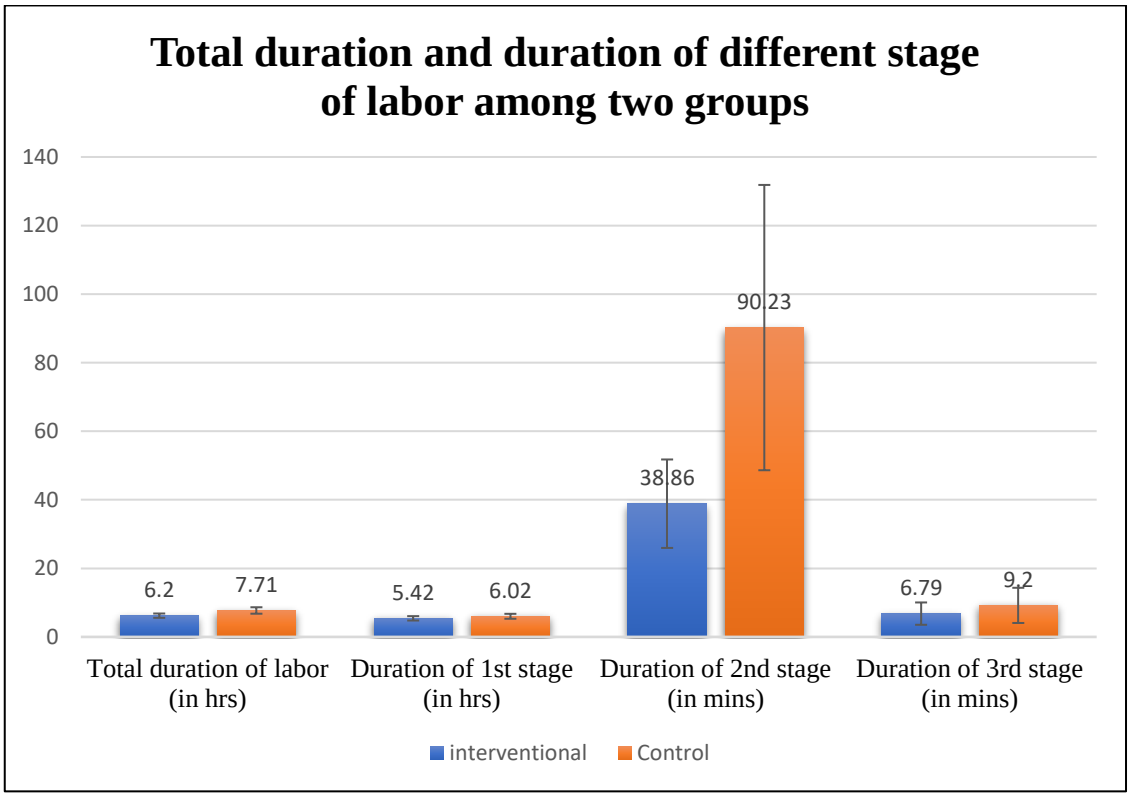


Figure 12: Bar diagram showing mean and SD of total duration of labor, duration of 1st stage, 2nd stage and 3rd stage of labor in intervention and control group

The figure above illustrates that the total duration of labor in the interventional group is 7.71 (±0.63) hours compared to 6.2 (±0.94) hours in the control group. Specifically, the duration of the first stage is 5.42 (±0.64) hours in the interventional group and 6.02 (±0.72) hours in the control group. Similarly, the duration of the second stage of labor is 38.86 (±12.90) minutes in the interventional group and 90.23 (±41.61) minutes in the control group.

2.1.4 Assessment of Childbirth Experience among pregnant women in interventional and control group.

Table no. 14

Mean and SD of childbirth experience among pregnant women in interventional and control group.

N=100

Group	Mean	SD
Experimental (n=50)	53.52	6.37
Control (n=50)	43.00	8.68

N= total no. of samples, SD= standard deviation,

Table above represented the mean and SD of total childbirth experience score in interventional and control group, in interventional group mean was 53.52 (SD±6.37) and 43 (SD±8.68, for control group respectively

Table no. 15

Frequency and percentage distribution of childbirth experience categories among pregnant women in interventional and control group.

N=100

Category	Experimental (n=50)		Control (n=50)	
	f	%	f	%
Positive (51-68)	**37**	74	10	20
Neutral (34-50)	12	24	**32**	64
Negative (17-33)	1	2	8	16

N= total no. of samples, f= frequency, % Percentage

As depicted in Table No. 15, the childbirth experience categories among pregnant women in the interventional and control groups reveal that the majority of pregnant women in the experimental group reported a positive childbirth experience (37, 54%), while in the control group, only 10 (20%) did so. Furthermore, the majority of women in the control group reported a neutral childbirth experience (24, 32%).

N=100

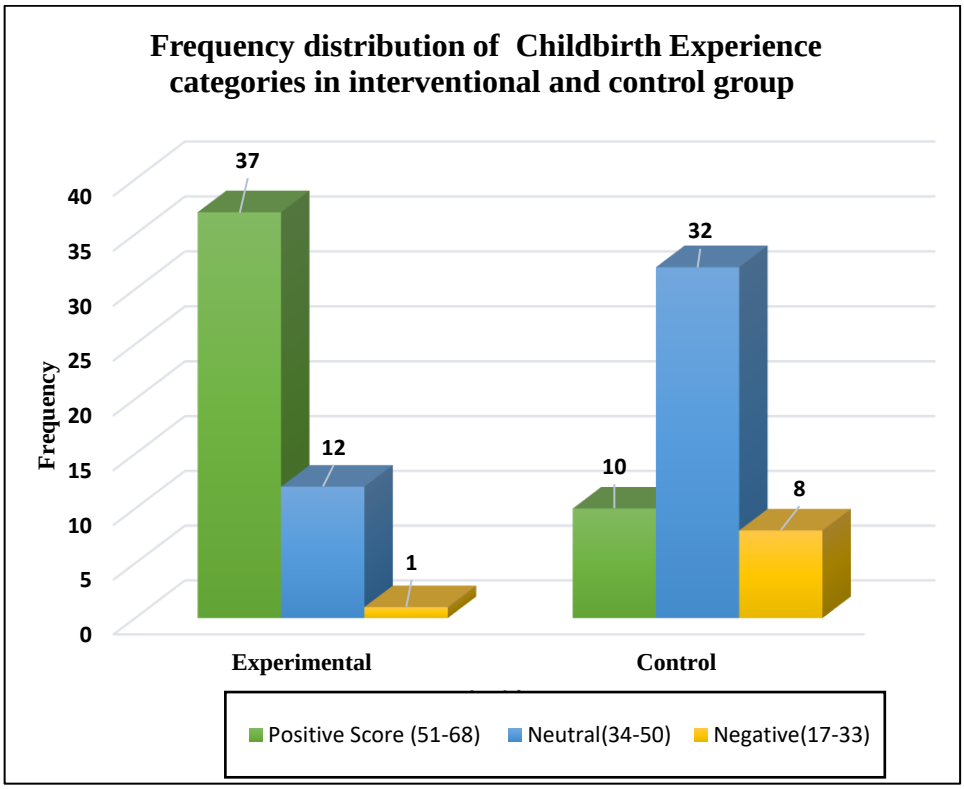


Figure no. 13 Bar diagram showing the frequency distribution of childbirth experience categories in interventional and control group

The data depicted that frequency of pregnant women in different categories of childbirth experience in experimental and control group. It shows that 37 pregnant women in experimental group was positive childbirth experience and 32 pregnant women in control group having neutral childbirth experience.

2.2 Findings related to the assessment of neonatal outcomes in the interventional and control group

Table no. 17

Frequency and percentage distribution of newborn status after birth, APGAR at 1 minute, APGAR at 5 minute and any birth complication among pregnant women who underwent Vaginal delivery in interventional and control group.

N=83

Maternal outcome	Categories	Experimental (n=43)		Control (n=40)	
		f	%	f	%
Newborn status at birth	Alive	**41**	95	**37**	93
	Asphyxiated	2	5	3	8
	Stillbirth	0	0	0	0
APGAR at 1 min	0-3	0	0	0	0
	04-06	7	16	10	25
	07-10	**36**	84	**30**	75
APGAR at 5 min	0-3	0	0	2	5
	04-06	0	0	1	3
	07-10	**43**	100	**37**	93
Any birth complication	Caput succedaneum	9	21	11	25.5
	Cephalo hematoma	0	23	0	0
	Minor scalp injuries	0	0	0	0
	Any other injuries	0	77	3	7.50
	No	**34**	79	**26**	65

N= total no. of samples, f= frequency, % Percentage

Table 17 shows that among the 50 pregnant women in the intervention group, 41 (95%) had live newborns, while 37 (93%) were observed in the control group. The majority of pregnant women in both the intervention group (36, 84%) and the control group (30, 75%) scored between 7-10 on the APGAR scale at 1 minute, majority of them have no birth complication 34 (79%) in intervention group and 26 (65%) in control group.

Section-3

Finding related to effectiveness of nurse led breathing exercise intervention protocol on labor outcome among pregnant women in intervention and control group

This section describes the effectiveness of nurse led breathing intervention protocol on the maternal and neonatal outcome in interventional and control group.

To statistically test the effectiveness of nurse led breathing intervention protocol on the maternal and neonatal outcome of pregnant women in interventional and control group the following null hypotheses were formulated and tested at .05 level of significance.

H01: There is no difference in maternal outcome among pregnant women of interventional group after the administration of Nurse led breathing exercise intervention protocol at 0.05 level of significance as measured by maternal outcome sheet and childbirth experience questionnaire.

H02: There is no difference in neonatal outcome among pregnant women of interventional group after the administration of Nurse led breathing exercise intervention protocol at 0.05 level of significance as measured by neonatal outcome sheet.

This section is divided into two subsections, with further subsections within each:

3.1 Finding related to effectiveness of nurse led breathing exercise intervention protocol on Maternal outcome among pregnant women in interventional and control group

The data is presented in Tables No. 18, 19, 20, 21, 23 and 24

3.2 Findings related to effectiveness of nurse led breathing exercise intervention protocol on neonatal outcome in interventional and control group

The data is being presented in table 25

Before testing the hypothesis, the normality of the data was assessed using the Kolmogorov-Smirnov test. The test revealed that the total duration of labor was normally distributed, while other variables such as oxytocin drop rate, duration of different stages of labor, and childbirth experience did not follow a normal distribution pattern.

3.1 Effectiveness of nurse led breathing exercise intervention protocol on Maternal outcome among interventional and control group

This sub division of section 2, describes effectiveness of nurse led breathing intervention protocol on the maternal outcome in interventional and control group.

3.1.1 Effectiveness of nurse led breathing exercise protocol on onset of labor, nature of progress of labor, mode of delivery among pregnant women in interventional and control group

Table no. 18

Comparison of onset of labor, nature of progress of labor, mode of delivery among pregnant women in interventional and control group

N=100

Maternal outcome	Categories	Interventional group(n=50)		control group(n=50)		χ^2 value	df	p-value
		f	%	f	%			
Onset of labor¥	Spontaneous	38	76.0	32	64.0	1.445	1	0.261
	Induced	12	24.0	18	36.0			
Nature of progress of labor¥	Progressed spontaneously	0	0.0	1	2.0	0.949	1	1.000
	Augmented	50	100.0	49	98.0			
Mode of delivery	Vaginal delivery	42	84.0	36	72.0	2.502	2	0.286
	Instrumental delivery	1	2.0	4	8.0			
	Emergency LSCS	7	14.0	10	20.0			

Chi-square test; ¥Fisher exact test, N= total no. of samples, f= frequency, % Percentage χ^2 chi-square test, df= degree of freedom

Table 18 presents the calculated χ2 values for the onset of labor at df 1, which was 1.445 with a corresponding p-value of 0.261 (higher than 0.05). For the nature of the progress of labor, the χ2 value was 0.949 with a p-value of 1.00 (higher than 0.05). Similarly, for the mode of delivery, the χ2 value was 2.502 with a p-value of 0.286 (higher than 0.05).

The findings from the table no.18 suggested that the nurse-led breathing intervention protocol implemented in the interventional group did not yield statistically significant

differences in the onset of labor, the nature of progress of labor, or the mode of delivery when compared to the control group p>0.05.

Testing hypothesis **H01:** There is no difference in maternal outcome among pregnant women of interventional group after the administration of Nurse led breathing exercise intervention protocol at 0.05 level of significance as measured by maternal outcome sheet and childbirth experience questionnaire.

The null hypothesis H01 was partly accepted in terms of onset of labor, nature of progress of labor and mode of delivery. These results suggest that, based on the variables assessed in this study, the nurse-led breathing intervention protocol may not have a substantial impact on the timing, progression, or mode of delivery in comparison to routine care.

3.1.2 Effectiveness of nurse led breathing exercise protocol on nature of vaginal delivery, expulsion of placenta, sign of PPH among pregnant women who underwent Vaginal delivery in interventional and control group.

Table no. 19

Comparison of nature of vaginal delivery, expulsion of placenta, sign of PPH among pregnant women who underwent Vaginal delivery in interventional and control group.

N=83

Maternal outcome	Categories	Interventional		Control		χ^2	df	p
		f (n=43)	%	f (n=40)	%			
Nature of vaginal delivery	**VD with episiotomy without laceration and tear**	28	65	22	55	2.268	3	0.519
	VD with episiotomy and laceration	4	9	5	12			
	VD with episiotomy and tear	5	12	9	23			
	VD without episiotomy	6	14	4	10			
Nature expulsion of placenta	**Spontaneous**	39	91	33	83	1.794	2	0.408
	Assisted	4	9	6	15			
	Manual removal	0	0	1	3			
Any sign of PPH¥	**Yes**	0	0	3	8	3.346	1	0.108
	No	43	0	37	93			

Chi-square test; ¥Fisher exact test, N= total no. of samples, f= frequency, % Percentage χ^2 chi-square test, df= degree of freedom

As indicated in Table 18, a total of 43 women in the intervention group and 40 in the control group underwent vaginal delivery, summing up to 83 pregnant women who delivered vaginally. Table 19, which compares the nature of vaginal delivery, expulsion of the placenta, and signs of PPH among these 83 women, reveals that the χ2 value was

2.268 with a p-value of 0.519 (higher than 0.05) for the nature of vaginal delivery. Additionally, for the sign of PPH, the $\chi 2$ value was 3.346 with a p-value of 0.108.

The nurse-led breathing intervention protocol did not result in statistically significant differences in the nature of vaginal delivery, expulsion of placenta, or signs of postpartum haemorrhage between the interventional and control groups ($p > 0.05$).

Testing hypothesis **H01:** There is no difference in maternal outcome among pregnant women of interventional group after the administration of Nurse led breathing exercise intervention protocol at 0.05 level of significance as measured by maternal outcome sheet and childbirth experience questionnaire.

The null hypothesis H01 was partly accepted in terms of nature of vaginal delivery, nature of expulsion of placenta and any sign of PPH. we can infer that the nurse-led breathing intervention protocol may not exert a substantial influence on the assessed outcomes related to the nature of vaginal delivery, placental expulsion, or signs of postpartum haemorrhage in comparison to routine care.

3.1.3 Effectiveness of nurse led breathing exercise protocol on total duration and duration of each stage of labor, oxytocin drop rate among pregnant women who underwent Vaginal delivery in interventional and control group.

Table no. 20

Comparison of , oxytocin drop rate and duration of different stage of labor in pregnant women who underwent Vaginal delivery in interventional and control group.

N=83

Variable	Groups	Mean rank	Mann-Whitney **U**	Z Value	p value
Oxytocin drop rate	interventional (n=43)	31.74	419	-4.092	<0.001*
	Control (n=40)	53.03			
Duration of 1st stage	interventional (n=43)	32.4	447	-3.776	<0.001*
	control (n=40)	52.33			
Duration of 2nd stage	interventional (n=43)	28.09	262	-5.581	<0.001*
	control (n=40)	56.95			
Duration of 3rd stage	interventional (n=43)	37.15	651	-1.985	0.047*
	control (n=40)	47.21			

*Significant at 0.05 level of significance, N= total no. of samples

Table above represented the comparison of mean and SD of oxytocin drop rate, duration of 1st stage, 2nd stage and 3rd stage of labor in interventional and control group, for duration of 1st stage of labor mean rank in intervention group was 32.4 and control group 52.33. Non- Parametric Mann Whitney test was applied as the dataset of particular variables do not follow normal distribution. Calculated Z value was -4.092 and p value was <0.01 (lass than 0.05) , for duration of 1st stage of labor Z value -3.776 and p value <0.01 (lesser than 0.05), for duration of 2nd stage of labor Z value was -5.581 and p value <0.01 (lesser than 0.05), Z value was –1.985 and p value 0.047 (lesser than 0.05) for duration of 3rd stage of labor.

Hence it was concluded that there was significant difference in oxytocin drop rate, duration of 1st stage, 2nd stage and 3rd stage of labor in both the groups interventional and control group.

Testing hypothesis **H01:** There is no difference in maternal outcome among pregnant women of interventional group after the administration of Nurse led breathing exercise intervention protocol at 0.05 level of significance as measured by maternal outcome sheet and childbirth experience questionnaire.

The null hypothesis H01 was partly rejected in terms of oxytocin drop rate, duration of 1st stage, 2nd stage and 3rd stage of labor. The significant differences in oxytocin drop rate and various stages of labor duration indicate that the intervention influenced the progression and management of labor in a manner distinct from the routine care provided to the control group. These findings contribute valuable insights into the potential efficacy and impact of the intervention on the specified labor parameters.

Table no. 21

Comparison of total duration of labor in pregnant women who underwent Vaginal delivery in interventional and control group.

N=83

Group	Mean (In hours)	SD	Mean difference	t	df	95% CI		P value
						Lower	Upper	
Interventional group (n=43)	6.20	0.63	1.51	8.661	81	1.85	1.16	<0.001*
Control group (n=40)	7.71	0.94						

*Significant at 0.05 level of significance, t- t test, df- degree of freedom, SD= standard deviation, CI= confidence interval, N= total no. of samples

The data given in table no. 13 shows the mean total duration of labor of the interventional group was 6.20 and 7.71 of control group with a difference of 1.51, Parametric unpaired t test was applied as the dataset of particular variables follow normal distribution. The independent sample t test suggests that there is significant difference in the mean of total duration of labor between the two groups.

Testing hypothesis **H01:** There is no difference in maternal outcome among pregnant women of interventional group after the administration of Nurse led breathing exercise intervention protocol at 0.05 level of significance as measured by maternal outcome sheet and childbirth experience questionnaire.

The null hypothesis H01 was partly rejected in terms of total duration of labor. The assumption of equal variance is upheld; however, the test provides evidence to reject null hypothesis of equal means between the groups. These findings contribute valuable

insights into the potential efficacy and impact of the intervention on the total duration of labor.

3.1.4 Effectiveness of nurse led breathing exercise protocol on Childbirth Experience in interventional and control group.

Table no. 22

Comparison of total childbirth experience score among pregnant women in interventional and control group.

N=100

Group	Mean rank	Mann Whitney U	Z Value	p-value
Experimental (n=50)	68.71	339.5	-6.295	<0.001*
Control (n=50)	32.29			

Mann Whitney test; N= total no. of samples, * indicates a significant difference at p≤0.05

Table above represented the mean rank for childbirth experience score in interventional and control group was 68.71 and 32.29 respectively.

Non- Parametric Mann Whitney test was applied as the dataset of particular variables do not follow normal distribution. Calculated Man Whitney value was 339.5 and p value was <0.001. Hence it was concluded that there was significant difference in childbirth experience score in both the groups interventional and control group.

Testing hypothesis **H01:** There is no difference in maternal outcome among pregnant women of interventional group after the administration of Nurse led breathing exercise intervention protocol at 0.05 level of significance as measured by maternal outcome sheet and childbirth experience questionnaire.

The null hypothesis H01 was partly rejected in terms of childbirth experience score. The significant differences in childbirth experience indicate that the intervention influenced the experience of labor in a manner distinct from the routine care provided to the control group.

Table no. 23

Comparison of childbirth experience categories among pregnant women in interventional and control group

N=100

Category	**Experimental (n=50)**		**Control (n=50)**		χ^2	**df**	**p-value**
	f	**%**	**f**	**%**			
Positive (51-68)	37	74	10	20	30.046	2	<0.001*
Neutral (34-50)	12	24	32	64			
Negative (17-33)	1	2	8	16			

Chi-square test, N= total no. of samples, f= frequency, % Percentage χ^2 chi-square test, df= degree of freedom , * indicates a significant difference at $p \leq 0.05$

As shown in table no. 23 Comparison of childbirth experience categories in pregnant women in interventional and control group , shown that χ^2 value for childbirth experience categories was 30.046 with $p < 0.01$.

The nurse-led breathing intervention protocol shows statistically significant differences in the childbirth experience categories between the interventional and control groups ($p < 0.05$).

Testing hypothesis **H01:** There is no difference in maternal outcome among pregnant women of interventional group after the administration of Nurse led breathing exercise intervention protocol at 0.05 level of significance as measured by maternal outcome sheet and childbirth experience questionnaire.

The null hypothesis H01 was partly rejected in terms of childbirth experience categories. we can infer that the nurse-led breathing intervention protocol exert a substantial influence childbirth experience in comparison to routine care.

3.1.5 Linear regression analysis of the effectiveness of nurse led breathing exercise intervention protocol on childbirth experience controlling for other independent variables in interventional and control group

Table no. 24

linear Regression analysis model on childbirth experience as dependent variable in interventional and control group

Regression	R	R^2	Constant	Unstandardized β	95% CI		p-value
					Lower	Upper	
Unadjusted	-0.637	0.406	66.110	-11.180	-14.169	-8.192	<0.001*
Model 1	-0.647	0.418	66.893	-10.167	-13.526	-6.809	<0.001*
Model 2	-0.678	0.460	77.495	-6.852	-11.067	-2.637	0.002*
Model 3	-0.722	0.521	86.349	-8.822	-13.008	-4.637	<0.001*
Model 4	-0.727	0.529	87.869	-8.644	-12.834	-4.455	<0.001*
Model 5	-0.734	0.539	90.104	-8.164	-12.405	-3.924	<0.001*

CI- confidence interval, * indicates a significant difference at p≤0.05

Linear regression analysis; Model 1: Adjusted for oxytocin drop rate; Model 2: Adjusted for oxytocin drop rate and Total duration of labor; Model 3: Adjusted for oxytocin drop

rate, Total duration of labor and Duration of 1st stage; Model 4: Adjusted for oxytocin drop rate, Total duration of labor, Duration of 1st stage and Duration of 2nd stage; Model 5: Adjusted for oxytocin drop rate, Total duration of labor, Duration of 1st stage, Duration of 2nd stage and Duration of 3rd stage.

The R-value represents the simple correlation and is -0.637 for the unadjusted CEQ value (the "R" Column), which indicates a strong correlation. For Adjusted CEQ values also showed a strong correlation between intervention group and CEQ values. The R^2 value (the "R Square" column) indicates how much of the total variation in the dependent variable, CEQ, can be explained by the independent variable. In the case of an unadjusted CEQ score, 40.6% can be explained, which is quite strong. Results of ANOVA test also showed that the regression model statistically significantly predicts the outcome variable (0<0.05).

Testing hypothesis **H01:** There is no difference in maternal outcome among pregnant women of interventional group after the administration of Nurse led breathing exercise intervention protocol at 0.05 level of significance as measured by maternal outcome sheet and childbirth experience questionnaire.

The null hypothesis H01 was partially rejected regarding childbirth experience. Therefore, we can infer that the nurse-led breathing intervention protocol significantly influences childbirth experience compared to routine care, even when controlling for all other possible influencing factors.

The study concludes that nurse led breathing exercises intervention protocol had a significant effect on maternal outcome of labor such as drop rate of oxytocin, Total duration of labor, 1st stage, 2nd stage of labor and 3rd stage of labor were minimized in the

intervention group. This proves that nurse led breathing exercise intervention protocol are an effective intervention to improve maternal labor outcomes

3.2 Effectiveness of nurse led breathing exercise intervention protocol on neonatal outcome in interventional and control group

Table no. 25

Comparison of newborn status at birth, APGAR at 1 minute, APGAR at 5 minute and any birth complication in pregnant women who underwent Vaginal delivery in interventional and control group.

N=83

Maternal outcome	Categories	Experimental (n=43)		Control (n=40)		χ^2	df	p-value
		f	%	f	%			
Newborn status at birth¥	Alive	41	95	37	93	0.297	1	0.668
	Asphyxiated	2	5	3	8			
	Stillbirth	0	0	0	0			
APGAR at 1 min¥	0-3	0	0	0	0	0.968	1	0.417
	04-06	7	16	10	25			
	07-10	36	84	30	75			
APGAR at 5 min	0-3	0	0	2	5	3.346	2	0.188
	04-06	0	0	1	3			
	07-10	43	100	37	93			
Any birth complication	Caput succedaneum	9	21	11	25.5	4.53	4	0.339
	Cephalo hematoma	0	23	0	0			
	Minor scalp injuries	0	0	0	0			

	Any other injuries	0	77	3	7.50
	No	34	79	26	65

Chi-square test; ¥Fisher exact test, N= total no. of samples, f= frequency, % Percentage χ^2 chi-square test, df= degree of freedom

Table no. 25 reports on newborn status, with a χ2 value of 0.297 and a p-value of 0.668 (higher than 0.05). For APGAR at 1 minute, the χ2 value was 0.968 with a p-value of 0.417 (higher than 0.05). Additionally, for any birth complication, the χ2 value was 4 with a p-value of 0.339 (higher than 0.05). The findings from the table no.25 suggested that the nurse-led breathing intervention protocol implemented in the interventional group did not yield statistically significant differences neonatal outcome (like p>0.05).

Testing hypothesis **H02:** There is no difference in neonatal outcome among pregnant women of interventional group after the administration of Nurse led breathing exercise intervention protocol at 0.05 level of significance as measured by neonatal outcome sheet.

As shown in table no. 25 ,Accept null hypothesis (H02) the p value for all neonatal outcome >0.05 level of significance. we can infer that the nurse-led breathing intervention protocol may not exert a substantial influence on the neonatal outcomes in comparison to routine care.

Although nurse led breathing exercise intervention protocol prove beneficial effect on maternal outcomes but did not demonstrate a significant difference in the neonatal outcome of labor.

Section 4

Finding related to association of the labor outcome with selected demographic variables

This section describes the association of the maternal and neonatal outcome with selected demographic variables

To statistically test the association of maternal and neonatal outcome with selected demographic variables, the following null hypotheses were formulated and tested at .05 level of significance.

H03: There is no significant association between selected demographic variables and maternal outcome at 0.05 level of significance

H04: There is no significant association between selected demographic variables and neonatal outcome at 0.05 level of significance

This section is divided into two subsections, with further subsections within each:

4.1 Finding related to association of Maternal outcome with selected demographic variable

The data is presented in Tables No. 26 and 27

4.2 Findings related to association of neonatal outcome with selected demographic variable

The data is being presented in table no. 28

4.1 Finding related Association between maternal outcome with selected demographic variable

Table no. 26

Association between effect of nurse led breathing exercise intervention protocol on maternal outcome with selected demographic variable

N=100

Characteristics		Experimental group (n=50)		Control group (n=50)	
		Onset of labor	Mode of delivery	Onset of labor	Mode of delivery
Education	χ^2	5.286	4.775	23.477	9.269
	p-value	0.259	0.781	0.059	0.507
Occupation	χ^2	6.675	5.091	7.775	6.753
	p-value	0.083	0.532	0.051	0.344
Residence	χ^2	0.118	1.295	0.506	2.223
	p-value	1.000	0.523	0.547	0.329
Religion	χ^2	4.243	2.039	6.249	2.319
	p-value	0.120	0.729	0.051	0.677
Type of family	χ^2	0.487	1.375	3.801	4.198
	p-value	0.784	0.849	0.068	0.123
Social support	χ^2	0.236	4.020	7.352	3.968
	p-value	0.889	0.403	0.061	0.681
Pregnancy planned	χ^2	0.025	0.680	7.203	1.485
	p-value	1.000	0.712	0.053	0.476

χ^2Chi-square test, N= total no. of samples,

As shown in above table 26 denoted the association of selected demographic variables with the maternal outcome. Chi square was used to determine the association. The p value for all the demographic variable found >0.05.

Testing hypothesis **H03**: There is no significant association between selected demographic variables and maternal outcome at 0.05 level of significance

The null hypothesis H03 was partly accepted, hence it was concluded that there was no association between education, occupation, residence, religion, family type, social support, planning of pregnancy with onset of labor and mode of in interventional and control group.

Table no. 27

Association between effect of nurse led breathing exercise intervention protocol on maternal outcome with selected demographic variable

N=83

Characteristics		**experimental group (n=43)**			**control group (n=40)**		
		Nature of vaginal delivery	**Nature of expulsion of placenta**	**PPH**	**Nature of vaginal delivery**	**Nature of expulsion of placenta**	**PPH**
Education	χ^2	13.960	1.478	.	27.380	6.712	3.604
	p-value	0.303	0.830	.	0.056	0.752	0.608
Occupation	χ^2	11.061	1.707	.	4.591	1.434	1.562
	p-value	0.272	0.635	.	0.868	0.964	0.668
Residence	χ^2	8.791	1.208	.	3.000	1.844	3.585
	p-value	0.062	0.272	.	0.392	0.398	0.058
Religion	χ^2	2.951	1.516	.	16.353	0.847	2.056
	p-value	0.815	0.469	.	0.062	0.932	0.358
Type of family	χ^2	12.393	0.105	.	2.200	1.939	0.360
	p-value	0.054	0.949	.	0.532	0.379	0.548
Social support	χ^2	0.543	6.916	.	10.036	2.391	2.462
	p-value	0.997	0.062	.	0.348	0.880	0.482
Pregnancy planned	χ^2	4.801	0.057	.	1.382	1.497	0.572
	p-value	0.187	0.811	.	0.710	0.473	0.449

χ^2Chi-square test, N= total no. of samples,

As shown in above denoted the association of selected demographic variables with the maternal outcome. Chi square was used to determine the association. The p value for all the demographic variable found >0.05.

Testing hypothesis **H03**: There is no significant association between selected demographic variables and maternal outcome at 0.05 level of significance

The null hypothesis H03 was partly accepted, hence it was concluded that there was no association between education, occupation, residence, religion, family type, social support, planning of pregnancy with nature of vaginal delivery and nature of expulsion of placenta of in interventional and control group.

The p value >0.05, hence it was concluded that there was no association between education, occupation, residence, religion, family type, social support, planning of pregnancy with maternal outcome in interventional and control group.

4.2 Association between neonatal outcome with selected demographic variables

Table no. 28

Association between effect of nurse led breathing exercise intervention protocol on neonatal outcome with selected demographic variable

N=83

Characteristics		Experimental (n=43)				Control (n=40)			
		the newborn born	APGAR at 1	APGAR at 5	complication	the newborn born	APGAR at 1	APGAR at 5	complication
Education	χ^2	1.768	7.676	.	2.151	4.324	8.933	5.824	26.679
	p-value	0.778	0.104	.	0.708	0.504	0.112	0.830	0.145
Occupation	χ^2	0.812	1.383	.	5.261	1.081	2.133	1.081	11.286
	p-value	0.847	0.710	.	0.154	0.782	0.545	0.982	0.505
Residence	χ^2	2.197	3.995	.	0.007	0.261	0.835	0.929	4.984
	p-value	0.233	0.095	.	1.000	1.000	0.473	0.628	0.289
Religion	χ^2	0.721	0.061	.	0.966	0.572	0.706	0.572	1.460
	p-value	0.697	0.970	.	0.617	0.751	0.703	0.966	0.993
Type of family	χ^2	2.197	0.374	.	4.579	0.360	0.533	1.027	4.500
	p-value	0.333	0.830	.	0.101	1.000	0.716	0.598	0.343
Social support	χ^2	1.410	0.607	.	0.355	0.300	3.911	3.606	9.696
	p-value	0.494	0.738	.	0.837	0.960	0.271	0.730	0.643
Pregnancy planned	χ^2	0.909	2.871	.	0.589	0.855	0.261	6.084	0.924
	p-value	1.000	0.172	.	0.458	0.394	1.000	0.048*	0.921

χ^2Chi-square test, N= total no. of samples,

As shown in above table 28 denoted the association of selected demographic variables with the neonatal outcome. Chi square used to determine the association. The p value >0.05

Testing hypothesis **H04:** There is no significant association between selected demographic variables and neonatal outcome at 0.05 level of significance

The null hypothesis H04 was accepted, hence it was concluded that there was no association between education, occupation, residence, religion, family type, social support, planning of pregnancy with neonatal outcome in interventional and control group.

The study concludes that nurse led breathing exercises intervention protocol had no significant association between selected demographic variables and neonatal outcome.

Summary

This chapter deals with the result of analysis of 100 pregnant women of a selected hospital of Bhopal. Both descriptive and inferential statistics data were used for data analysis. The statistical tests employed were proportion and diagrams were test. Tables, Bar graphs, to depict the demographic, maternal and neonatal outcome.

The next chapter present the discussion, major finding, conclusion, implication, limitation and recommendation.

CHAPTER- V

DISCUSSION

Introduction

The present study was intended to measure the effect of nurse led breathing exercise intervention protocol on labor outcome among pregnant women of selected tertiary care hospitals of Bhopal. A randomized controlled trial, post-test prospective randomized controlled trial was aptly used to execute intend of the study. Sample size consist of 100 pregnant women i.e., 50 pregnant women in interventional group and 50 in control group. Baseline assessment along with details about demographic variables was done. Nurse led breathing exercise intervention protocol was implemented for interventional group pregnant women. Post test was conducted at the time of labor and childbirth experience at the time of early postnatal period. Data analysis was done.

This chapter dealt with the summary of the study, highlights of major finding, implication, strength, limitation and recommendation for further studies.

Objectives of the study

1. To develop and administer nurse led breathing exercise intervention protocol to the Interventional group.
2. To assess the effect of nurse led breathing exercise intervention protocol on labor outcomes in terms of maternal and neonatal outcome among pregnant women.
3. To find association between labor outcome with selected demographic variables among pregnant women.

Hypothesis

1. **H01:** There is no difference in maternal outcome among pregnant women of interventional group after the administration of Nurse led breathing exercise intervention protocol at 0.05 level of significance as measured by maternal outcome sheet and childbirth experience questionnaire.
2. **H1:** There is significant difference in maternal outcome among pregnant women of interventional group after the administration of Nurse led breathing exercise intervention protocol at 0.05 level of significance as measured by maternal outcome sheet and childbirth experience questionnaire.
3. **H03:** There is no significant association between selected socio-demographic variables and maternal outcome at 0.05 level of significance
4. **H02:** There is no difference in neonatal outcome among pregnant women of interventional group after the administration of Nurse led breathing exercise intervention protocol at 0.05 level of significance as measured by neonatal outcome sheet.
5. **H3:** There is significant difference in neonatal outcome among pregnant women of interventional group after the administration of Nurse led breathing exercise intervention protocol at 0.05 level of significance as measured by neonatal outcome sheet.
6. **H04:** There is no significant association between selected socio-demographic variables and neonatal outcome at 0.05 level of significance

Major findings of the study

Major findings of the study are as follow

1. **Finding related to description of the samples (Pregnant women) according to their demographic characteristics**

- The mean age of women in the intervention group was 24.88 (SD ±3.91) years, and that of control group was 23.64 (SD±3.16) years.
- 13 (26%) of samples in interventional group were educated up to high school certificate and 16 (32%) samples in control group were educated up to graduate.
- Maximum of the samples 35(70%) in both the group were housewife, Majority of the women from both the groups intervention 43 (86%) and control group 38 (76%) belonged to Hindu religion,
- Lived in nuclear family interventional group 26 (52%) and control group 32 (64%), for majority of pregnant women of intervention group 19(38%) have in laws as social support and in control group 20(40%) have parents,
- None of the participant have smoking habit and majority of women have present pregnancy is unplanned 42 (84%) in interventional group and 35(70%) in control group
- The mean period of gestation at which pregnant women were recruited/ enrolled for the study in the intervention group was 36.04 (SD±0.58) weeks, and that of control group was 35.94 (SD±0.443) weeks.

2. **Findings related to the assessment of labor outcomes in the intervention and control group in terms of maternal and neonatal outcomes**

- Among 50 pregnant women in intervention group 38 (76%) had spontaneous onset of labor. As compared to the control group out of 50 only 32 (64%) pregnant women had spontaneous onset of labor.
- Majority of the pregnant women both in interventional group 50 (100%) and control group 49(98%) have progress of labor was augmented by the use of methods such as oxytocin, prostaglandins, overall rate of vaginal delivery in interventional group 42(84%) and 36(72%) in control group followed by caesarean delivery 7(14%) in interventional group and 10(20%) in control group.
- Majority of delivered normal vaginal delivery with episiotomy without laceration and tear in interventional group 28(65%) and 22 (55%) in control group, most of delivered placenta spontaneous 39(91%) in intervention group and 33(83%) in control group. Majority have no sign of PPH in both the groups.
- Oxytocin drop rate in interventional group mean was 32.00 (SD±18.85) and 50.05 (SD±15.86), for control group respectively,
- Mean duration of 1st stage of labor mean 5.42 hours (SD±0.64) in interventional group, 6.02 hours (SD±0.72) in control group whereas mean total duration of labor of the interventional group was 6.20hours (SD±0.63) and 7.71hours (SD±0.94) of control group
- The mean childbirth experience score in the interventional group was 53.52 (SD ± 6.37), compared to 43 (SD ± 8.68) in the control group. The majority of pregnant women experienced positive childbirth in the interventional group (37, 74%), whereas in the control group, the majority experienced a neutral childbirth experience (32, 64%).

- Among 50 pregnant women in intervention group 41 (95%) had newborn alive and 37 (93%) in control group. Majority of the pregnant women both in interventional group 36 (84%) and 30 (75%) in control group have score 7-10 of APGAR at 1minute

3. Finding related to effectiveness of nurse led breathing exercise intervention protocol on labor outcome among pregnant women in intervention and control group

- Nurse-led breathing intervention protocol implemented in the interventional group did not yield statistically significant differences in the onset of labor, the nature of progress of labor, or the mode of delivery, nature of vaginal delivery, expulsion of placenta and sign of PPH when compared to the control group $p>0.05$.
- Nurse led breathing exercise intervention protocol significantly improved the oxytocin drop rate, duration of each stage of labor and overall duration of labor in interventional group as evident by the Z value for oxytocin drop rate ($Z=-4.092, p<0.001$), duration of 1st stage of labor ($Z= -3.776, p <0.01$), duration of 2nd stage of labor ($Z = -5.581, p <0.01$), 3rd stage of labor ($Z=–1.985$, p 0.047), total duration of labor ($t_{(81)}= 8.661, p<0.001$)
- Subsequently the comparison of childbirth experience score in experimental and control group was done by Mann-Whitney test, the mean rank 68.71 in intervention group and 32.29 in control group. The Z value was -6.295, $p<0.01$, hence the finding contributes valuable insight into the potential efficacy and impact of intervention on specified labor outcome including childbirth experience.
- Results of linear regression test childbirth experience as dependent variable also showed that the regression model statistically significantly predicts the outcome variable ($0<0.05$).

- p value for all neonatal outcome >0.05 level of significance, nurse-led breathing intervention protocol may not exert a substantial influence on the neonatal outcomes in comparison to routine care.

4. Finding related to association of the labor outcome with selected demographic variables

- The nurse-led breathing exercises intervention protocol exhibited no significant association between selected demographic variables and labor outcomes ($p > 0.05$).

Discussion of the finding

Description of Sample demographic characteristics

The intervention and control groups' pregnant women were similar in terms of their age, POG at Enrollment, occupation, place of residence, religion, family structure, social support, planned pregnancy, and labour onset. The women in the intervention group in this study had an average age of 24.88 (SD ±3.91) years, while the women in the control group had an average age of 23.64 (SD ±3.16) years. Participants in similar age groups were quoted in research from Turkey([16,67]), Northern India [75]. Conversely, research has shown that pregnant women in higher age groups participated in studies conducted in Australia and India [22,76]

The majority of pregnant women in the intervention group possessed a high school certificate, comprising 13 individuals (26%), while in the control group, 16 participants (32%) held graduate-level qualifications. Similar educational distributions were observed in characteristic studies conducted in various regions. For instance, Kaur et al. [75]noted

comparable findings in India, Lavett et al. [90] in Australia, and Cicek ([16] in Turkey. Conversely, studies conducted by Prince et al. [77]in Australia and Abdullah et al. [92] in Iraq reported differing educational profiles.

The majority of pregnant women in the intervention group, totalling 35 individuals (70%), were identified as homemakers. Consistent with these findings, several studies also reported a predominance of homemakers among pregnant women participants [22, 81, 89].

The mean gestation period of the primigravid women recruited and enrolled for the study was 36.04 (SD±0.830) weeks for the intervention group and 35.94 (SD±0.443) weeks for the control group. These values were comparable to the mean gestation period of 37.8±1.2 weeks for the experimental group and 37.5±1.2 weeks for the control group. ([89] In a study by Hjelmstedt (2010) [92] the massage group's mean gestational age was 38.65±0.91 weeks, while the control group's was 39.07±0.83 weeks.

Labor outcomes in terms of maternal and neonatal outcomes

In the current investigation, among the 50 pregnant women in the intervention group, 38 individuals (76%) experienced a spontaneous onset of labor. In contrast, among the 50 participants in the control group, only 32 women (64%) had a spontaneous onset of labor. These results align with those of a study conducted in southern India, where 98 out of 140 participants (70%) in the intervention group also had a spontaneous onset of labor [22] and study conducted in Australia.[76]

The majority of pregnant women in the interventional group delivered vaginally, accounting for 42 individuals (84%). This trend was consistent with findings from studies conducted in various locations. For instance, in studies from Karnataka, India [22], 67

individuals (48%) delivered vaginally. Similarly, in Australia[76], approximately 68.2% of participants delivered vaginally, while in Sweden[78], the proportion was 73.3%.

The first stage of labour lasted 5.42 hours (±0.64) in the intervention group and 6.02 hours (±0.72) in the control group. These results are consistent with research done by Levett et al. (76)to evaluate the impact of complementary therapies on labour and the length of time it took to give birth during the first stage of labour. The duration of the active phase of labour was found to be 174 (±69.90) hours in the intervention group in the study by Cicek et al. [16], which assessed the effect of breathing technique training on labour duration. Additionally, the experimental group showed a higher average duration of the first stage of labour, at 8.8 hours (±0.9), with a range of 7.45 to 11.20 hours [89].

Duration of 2nd stage of labor was 38.86 minutes in intervention group and 90.23 minutes in control group. The same average duration find in study conducted in Australia (76), studies from Northern India [75] and Turkey (16) reported less average duration of 2nd stage of labor.

The majority of pregnant women in the intervention group, totalling 37 individuals (74%), reported experiencing a positive childbirth. This aligns with findings from another study where a significant proportion of pregnant women, after receiving psychoprophylaxis intervention during labor, also reported an overall positive childbirth experience, comprising 237 individuals (48.9%).[78]

Effectiveness of nurse led breathing exercise intervention protocol on outcome of labor

According to the present study, the nurse-led breathing exercise intervention protocol may not have a substantial impact on the onset of labor ($\chi2$=1.445,df=1,p=0,261)and mode of delivery ($\chi2$=2.502, df=2, p=0.286). However, in contrast to this finding, a study conducted in Karnataka, India (22)demonstrates a statistically significant difference in onset of labor (OR=2.192, 95% CI 1.313-3.361) and the nature of delivery between the experimental and control groups ($p < 0.001$), A cross sectional study was done in India also contradict the findings of the present study that antenatal exercises facilitate normal labor, where 148 (74%) of women had normal vaginal delivery and 52 (26%) had caesarean deliveries ($\chi2$=27.599, df=1,p <0.001, RR= 2.287, 95% CI 1.611-3.246)(79)

The results of the current study indicate a statistically significant reduction in the mean duration of labor among pregnant women who participated in the nurse-led breathing exercise intervention protocol compared to those who did not attend (Mean difference=1.51, t_{81}=8.66, pvalue<0.05), These findings align with prior interventional research, such as the study by Karkada et al. (22)which reported a clinically and statistically significant difference in mean labor duration (in hours) between the intervention group (5.5127, SD 1.998 hours) and the standard care group (7.238 ± 3.678 hours), resulting in a mean difference of 132 minutes ($p < 0.001$). Similarly, Chuntharapat's trial results showed that women who practiced yoga had much shorter labour periods overall and during the first stage of labour (63)Further research has consistently demonstrated favourable results; for example, one study found that pregnant yoga practitioners had higher expectancies for outcomes and self-efficacy in the active and second stages of labour ($p =.002$, $p < 0.01$, respectively) ([80])

In present study revealed that there is significant difference in childbirth experience between experimental and control group at (Mann Whitney U= 339.5, z= 6.295, p<o0.001).. In contradict to this, study RCT conducted at Sweden, Bergstrom et al. to assess the whether the use of psychoprophylaxis during affect course of labor and childbirth experience revealed that there was no difference in experience of childbirth between the group p>0.05.[78]

There is no significant difference in neonatal outcome between experimental and control group (baby cried immediately after birth, APGAR At 1 min, at 5 min and immediate complication. The present study reported no significant difference in the APGAR Score(p>0.05)at 1 and 5 min ($\chi 2$=0.968, df=1,p=0.417), In congruent to this, study conducted by Karkada SR et al. in Karnataka, India revealed also no significant difference in APGAR at 1 and 5 minute between two group.[22] and study conducted by Yuksel in Turkey also shows no significant difference in APGAR at 1 minute between two groups (p>0.05) .Contradict finding in e. Gehan et al (2015) reported a statistical significant difference in mean value of APGAR score at first minute as 7.32 in the intervention group and 6.64 in the control group (Z=3.965,p <0.01)([81])

Implications

The findings of the study have implications for nursing practice, nursing education, nursing administration and nursing research.

Nursing practice

Nurses and childbirth educators play a vital role in providing comprehensive childbirth education, aligning with the philosophy of natural childbirth with minimal interventions to reduce risks for both mother and baby. They should offer supportive, continuous care to empower women throughout the childbirth process, allowing them to choose from various childbirth strategies. Providing accessible information about prenatal care and emotional preparation for childbirth enhances women's confidence during delivery. Nurses should adeptly address any concerns or fears and foster feelings of empowerment in expectant women. Offering evidence-based recommendations on relaxation techniques and providing post-birth support and networking opportunities for new parents are essential aspects of nursing care across all settings. Nurses can integrate breathing exercises into their practice to support women during labor, potentially reducing the need for medical interventions and promoting positive birth experiences.

Nursing education

Community-based education and practice form an essential component of nursing education, empowering nurses to provide comprehensive pregnancy education that prepares families for childbirth and beyond. This includes supporting women during labor, monitoring both mother and baby, offering coaching, and assisting throughout the birthing process. Nurse educators play a pivotal role in shaping the future of nursing by upholding rigorous standards of practice and ensuring ongoing compliance through tailored training and education programs. Nurses must rigorously evaluate program effectiveness based on the quality of learning activities and teacher-student interactions to facilitate genuine education. Nursing students can be educated on the importance of non-pharmacological interventions during labor and taught how to effectively implement breathing exercises in clinical settings. Additionally, they must continually enhance

problem-solving, decision-making, and critical-thinking skills to meet evolving healthcare needs.

Nursing research

Nursing research plays a pivotal role in shaping current and future professional nursing practice, making it a cornerstone of nursing education. In the 21st century, nurses operate across diverse settings, from hospitals and classrooms to community health departments and laboratories. Despite the variation in roles, the fundamental objective of a professional nurse remains consistent: to advocate for clients and deliver optimal care based on evidence gleaned from research.

The evidence-based practice framework serves to enhance the quality and safety of care by prompting nurses to scrutinize existing practices using a structured decision-making process. Combining this framework with an active-learning approach facilitates the development of educational interventions aimed at driving practice change and addressing the learning needs of labor and delivery professionals.

Strength

Methodology:

- This study utilizes randomized controlled trial which generates strongest evidence.(level 2 in evidence pyramid)
- This study has included the calculated sample, which acts as a representative sample for the population. Hence, the result can be generalized.

Outcome assessed:

- This study assesses the effectiveness of nurse-led breathing exercise intervention on all possible labor outcomes including childbirth experience. There is limited literature available regarding the same.

Limitation

- Within the data collection period, the outcome of all enrolled sample could not be assessed
- Few enrolled samples' labor outcome could not be assessed due to the inability to be present at a given time in both settings.

Challenges

- Sometimes mothers were resistant considering practice of exercise at home as additional burden but due course and by understanding its benefits women become so cooperative.
- Physically presence throughout the process of labor for all participants is sometimes really difficult.

Recommendation

1. A Comparative study may be conducted to find the effectiveness of breathing exercise intervention be done between primigravida and multigravida pregnant women.
2. A qualitative study may conduct to explore the mother birth experience after receiving nurse-led intervention protocol.

3. An experimental study may be conducted to assess the Effectiveness of antenatal breathing exercises on maternal stress, and anxiety.
4. An observational study may be conducted to assess the feasibility, usability, and utilization of such technology-based intervention among pregnant women.

Reflection of the research study

The researcher had a great opportunity to learn new things as a beginner researcher and to think back on the study that she had conducted. According to the researcher, reflection ought to be a continuous process that is carried out for use as an enduring learning tool in both personal and professional contexts. beginning with the choice of problem statement and ending with the submission of the completed dissertation. Every turning point in this voyage has brought back a wealth of knowledge and memories.

One of the topics that the researcher was curious to learn more about when she was a student worker was, "Why are we not doing anything by ourselves or is there any simple method which reduce pain, trouble of labouring women?" This inquiry resulted from the contemplation procedure, and it was the start of developing the concept of carrying out research in this area. That was not the end of the process of critical reflection. In fact, it evolved and persisted during the course of this investigation, and it was incorporated into the study by keeping reflective journals. The researcher's development of a roadmap for childbirth education in India, a non-pharmacological approach of labour management, a film and booklet, and a comprehensive breathing exercise routine was made possible by constant critical reflection and appropriate assistance. The researcher faced a great hurdle when deciding to conduct this investigation using a randomised controlled trial approach.

She had never used the RCT process before, but she did have experience with quantitative descriptive research. It was interesting and taught me something new.

The researcher found the entire process of carrying out this study to be both interesting and surprising at every turn. Being with the mother and managing two hospitals for data collection is another major challenge during the study. The researcher knew the planned procedure for gathering data and developing intervention, but she had never considered how it would be applied in real life. The plan to do a regression test to assess the dependent variable was also a great challenge.

As a result, the whole experience was fulfilling because it involved more than just doing research. It started a lifetime learning endeavour that drew on a variety of sources, including study participants, supervisors, and the researcher's own self-learning methodology, in order to provide a researcher with enough expertise to handle any research activities.

Conclusion

Study underscores the significant impact of such interventions in enhancing labor outcomes. Through rigorous implementation and evaluation, we have demonstrated that nurse-led breathing exercises can positively influence labor outcomes, including reducing the duration of labor, minimizing the need for medical interventions, and enhancing overall maternal and neonatal well-being.

The findings of this study emphasize the importance of integrating nurse-led breathing exercise protocols into routine antenatal care, as they offer a safe, cost-effective, and non-invasive approach to labor management. By empowering pregnant women with effective

breathing techniques and support during labor, nurses can contribute significantly to improving birth experiences and promoting positive maternal and neonatal health outcomes.

Moving forward, further research is warranted to explore the long-term effects and sustainability of nurse-led breathing exercise interventions on labor outcomes. Additionally, efforts should be made to integrate these interventions into standard practice guidelines and healthcare policies to ensure widespread accessibility and adoption among pregnant women and healthcare providers. Ultimately, by harnessing the potential of nurse-led breathing exercises, we can strive towards enhancing the quality of maternity care and optimizing childbirth experiences for women worldwide.

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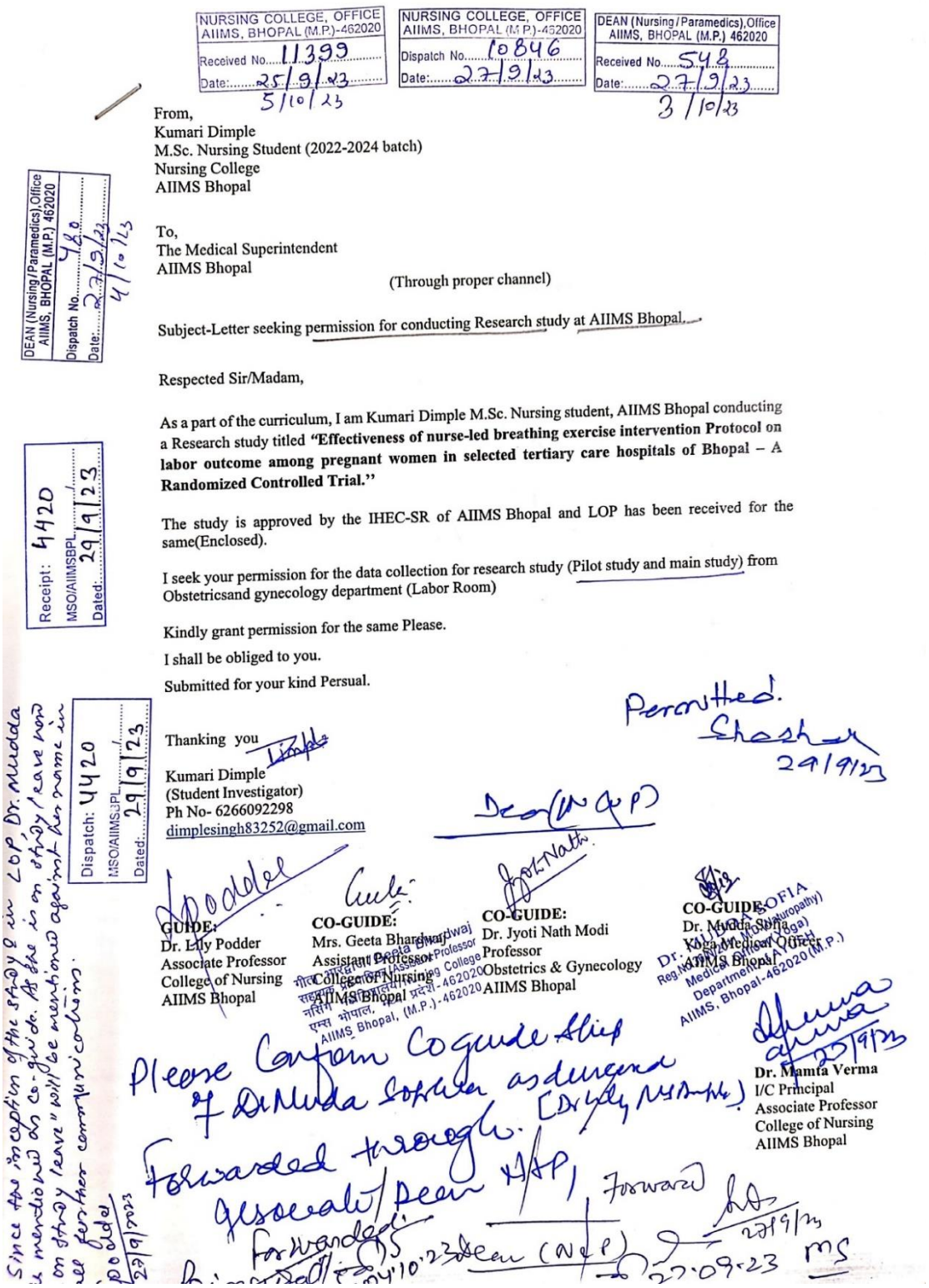
Annexure-1

Letter seeking permission to conduct the study



NURSING COLLEGE, OFFICE AIIMS, BHOPAL (M.P.)-462020
Received No. 11399
Date: 25/9/23
5/10/23

NURSING COLLEGE, OFFICE AIIMS, BHOPAL (M.P.)-462020
Dispatch No. 10846
Date: 27/9/23

DEAN (Nursing/Paramedics), Office AIIMS, BHOPAL (M.P.) 462020
Received No. 548
Date: 27/9/23
3/10/23

From,
Kumari Dimple
M.Sc. Nursing Student (2022-2024 batch)
Nursing College
AIIMS Bhopal

DEAN (Nursing/Paramedics), Office AIIMS, BHOPAL (M.P.) 462020
Dispatch No. 548
Date: 27/9/23
4/10/23

To,
The Medical Superintendent
AIIMS Bhopal
(Through proper channel)

Subject-Letter seeking permission for conducting Research study at AIIMS Bhopal.

Respected Sir/Madam,

As a part of the curriculum, I am Kumari Dimple M.Sc. Nursing student, AIIMS Bhopal conducting a Research study titled **"Effectiveness of nurse-led breathing exercise intervention Protocol on labor outcome among pregnant women in selected tertiary care hospitals of Bhopal – A Randomized Controlled Trial."**

Receipt: 4420
MSO/AIIMSBPL
Dated: 29/9/23

The study is approved by the IHEC-SR of AIIMS Bhopal and LOP has been received for the same(Enclosed).

I seek your permission for the data collection for research study (Pilot study and main study) from Obstetricsand gynecology department (Labor Room)

Kindly grant permission for the same Please.

I shall be obliged to you.

Submitted for your kind Persual.

Dispatch: 4420
MSO/AIIMSBPL
Dated: 29/9/23

Thanking you

Kumari Dimple
(Student Investigator)
Ph No- 6266092298
dimplesingh83252@gmail.com

Permitted.
Thanks
29/9/23

Dean (N&P)

GUIDE:
Dr. Lily Podder
Associate Professor
College of Nursing
AIIMS Bhopal

CO-GUIDE:
Mrs. Geeta Bhardwaj
Assistant Professor
College of Nursing
AIIMS Bhopal

CO-GUIDE:
Dr. Jyoti Nath Modi
Professor
Obstetrics & Gynecology
AIIMS Bhopal

CO-GUIDE:
Dr. Mudra Sojitra (Naturopathy)
Yoga Medical Officer
AIIMS Bhopal

Dr. Mamta Verma
I/C Principal
Associate Professor
College of Nursing
AIIMS Bhopal

Since the inception of the study & in LOP, Dr. Mudra is mentioned as co-guide. As she is on study leave now on study leave will be mentioned against her name in further communications.

Please Confirm Co guide Slip of Dr Mudra Sojitra as mentioned Forwarded through. Dr (Dy MS-Admn)

Forwarded Dean (N&P)

Forwarded

Dean (N&P) 27.09.23 MS

Annexure-2
Letter seeking permission to conduct the study

कार्यालय मुख्य चिकित्सा एवं स्वास्थ्य अधिकारी, जिला भोपाल

Email id-cmhobho@nic.in

क्रं./अ.प्रशा./2023/16764 भोपाल दिनांक12/10/2023

प्रति

प्राचार्य,
कॉलेज ऑफ नर्सिंग,
ऐम्स, भोपाल ।

विषयः– अध्ययन की अनुमति दिये जाने के संबंध में ।
संदर्भः– प्राचार्य, कॉलेज ऑफ नर्सिंग, ऐम्स, भोपाल का पत्र क्रं./11398 दिनांक 27.09.2023

विषयांतर्गत लेख हैं, कि संदर्भित पत्रानुसार आपके द्वारा एम.एस.सी. नर्सिंग पाठ्यक्रम के अन्तर्गत रिसर्च विषय **"Effectivenss of nurse-led breathing exercise intervention Protocol on labor outcome among pregnant women in selected tertiary care hospitals of Bhopal – A Randomized Controlled Trail"** के अन्तर्गत जयप्रकाश चिकित्सालय, भोपाल में Obstetrics and gynecology department (Labour Room) में अध्ययन हेतु निम्नांकित शर्तों के अधीन अनुमति दी जाती है ।

1. अध्ययन से संबंधित/शामिल किसी भी व्यक्ति की व्यक्तिगत जानकारी को सार्वजनिक नहीं किया जायेगा ।
2. अध्ययन से संबंधित किसी भी शोध प्रबंध को सार्वजनिक/प्रकाशित किये जाने हेतु अधोहस्ताक्षरकर्ता से लिखित पूर्वानुमति आवश्यक होंगी ।
3. यह कार्य पूर्णतः स्वैच्छिक होगा तथा इस कार्य हेतु कोई भुगतान नहीं किया जायेगा ।

मुख्य चिकित्सा एवं स्वास्थ्य अधिकारी
जिला–भोपाल
भोपाल दिनांक 12/10/2023

पृ.क्रं./अ.प्रशा./2023/16765
प्रतिलिपिः–की ओर सूचनार्थ ।

1. आयुक्त सह सचिव स्वास्थ्य संचालनालय स्वास्थ्य सेवायें, म0प्र0, भोपाल ।
2. मिशन संचालक, राष्ट्रीय स्वास्थ्य मिशन, मध्यप्रदेश, लिंक रोड़ नं0 3, भोपाल।
3. कलेक्टर, जिला–भोपाल ।
4. सिविल सर्जन सह मुख्य अस्पताल अधीक्षक, जयप्रकाश चिकित्सालय, भोपाल ।
5. कु. डिम्पल, एम.एस.सी. नर्सिंग छात्र, नर्सिंग कॉलेज, ऐम्स, भोपाल ।

मुख्य चिकित्सा एवं स्वास्थ्य अधिकारी
जिला–भोपाल

Jonathan/Nursing/303

Annexure-3

Sample size calculation- Power analysis

The openepi software

Sample size for comparing two means

Sample size for the study of effectiveness of nurse led breathing exercise intervention protocol on labor outcome among pregnant women of selected tertiary care hospitals of Bhopal.

Sample Size For Comparing Two Means				
Input Data				
Confidence Interval (2-sided)		95%		
Power		80%		
Ratio of sample size (Group 2/Group 1)		1		
	Group 1		**Group 2**	**Difference***
Mean	5.51		7.23	-1.72
Standard deviation	1.99		3.67	
Variance	3.9601		13.4689	
Sample size of Group 1		47		
Sample size of Group 2		47		
Total sample size		94		
*Difference between the means				

Results from OpenEpi, Version 3, open source calculator--SSMean.

Required sample size for the study: 100 (50 in each group)

Based on the literature data: in reference article showed that Effectiveness of antepartum breathing exercises on the outcome of labour, the pregnant women had a significantly less mean total duration of labor after participating in the study(mean=5.51 hrs and SD= 1.99) with compare to control group (mean=7.23 hrs and SD= 3.67). here we use minimum 80% power value and 95% of CI and result of minimum sample size per group 47 and consider 50 in each group. Thus require sample size 100 i.e. 50 in each group.

Reference article: "Effectiveness of antepartum breathing exercises on the outcome of labour: A randomized controlled trial" by Karkada SR, Noronha JA, Bhat SK et al. of department Manipal College of Nursing, Manipal Academy of Higher Education,

Manipal, Karnataka, 576104, India. In F1000Research 2023, 11:159
https://doi.org/10.12688/f1000research.75960.3

Annexure-4

DATA COLLECTION TOOL (ENGLISH)

Section A: Screening tool for data collection

Serial no. …….

Date of assessment:

Address:

Contact number:

Instruction: encircle the appropriate response.

1.	Is Women pregnant for the first time (Primigravida)	**Yes**	**No**
2.	Is Pregnant women above the age of 18 years	**Yes**	**No**
3.	Whether the client understand Hindi, English or both?	**Yes**	**No**
4.	Whether the client is willing to participate or giving informedconsent?	**Yes**	**No**
5.	Is Pregnant women between 35weeks- 36+6 days period of gestation	**Yes**	**No**
6.	women having not any medical & surgical complication which might complicate the pregnancy as per case sheet.	**Yes**	**No**
7.	Is Pregnant women is mentally sound as per case sheet	**Yes**	**No**
8.	Is Pregnant women have smart phone and know how to use it	**Yes**	**No**
9.	Is pregnant women taking any childbirth preparation classes	**Yes**	**No**

Inference: Include/ Exclude

SECTION B – PART I

SOCIO- DEMOGRAPHIC VARIABLE PERFORMA

Instructions

- Please Read carefully and put ✓ Mark in front of given option

Participant identification number ……...

1. Age ……...
2. Education (Kuppuswamy's Scale)

a) Profession or Honours

b) Graduate

c) Intermediate or Diploma

d) High School Certificate

e) Middle school Certificate

f) Primary school Certificate

g) Illiterate

3. Occupation

a) Home maker

b) Professional

c) Self employed

d) Work from home

4. Residence

a) Rural

b) Urban

5. Religion

a) Hinduism

b) Christianity

c) Islam

d) Others

6. Type of family

a) Nuclear

b) Joint

7. Who are your social support

a) Husband

b) Parents

c) In laws

d) Relatives

e) Any other , if yes then specify

8. Do you have smoking habit

a) Yes

b) No

9. Is your Pregnancy planned

a) Yes

b) No

SECTION A – PART II

CLINICAL VARIABLE PERFORMA

Instruction: Note down the appropriate data for filling the clinical details of study participant .

At 1st contact

Participant identification number _____

Date …….

- LMP --------
- EDD --------
- POG --------
- Any past medical history and surgical history ……
- Any medical disorder happens during pregnancy ……

At subsequent contact

- POG ……..

Present Chief complaint …….

SECTION 2 - PART III

LABOR OUTCOME SHEET PERFORMA

Instruction for student investigator:

- **Observe the women in 1st, 2nd and 3rd stage of labor**
- **Check the most appropriate option from each of the given criteria of labor outcome.**

Participant identification number …….

Date:

Maternal outcome		Yes	No	remark
1. POG at onset of true labor –				
2. Onset of labor	Spontaneous (1)			
	Induced (0)			
3. Nature of progress of labour	Progressed Spontaneously			
	Augmented by any method			
	If augmented the method used:			
	- Oxytocin and its dose and drops			
	- Prostaglandin			
	- Low rupture of the membrane			
	- Any medication used for pain relieving, if yes please mention name, dosage and frequency of medication.			
4. Mode of delivery	Vaginal delivery. (If yes then Point no. 5 and onward)			
	Instrumental delivery (forceps, vacuum)			

	Emergency LSCS				
5. Nature of vaginal delivery	Normal vaginal delivery with episiotomy without laceration and tear.				
	Normal vaginal delivery with episiotomy and laceration.				
	Normal vaginal delivery with episiotomy and tear.				
	Normal vaginal delivery without episiotomy				
6. Nature of expulsion of placenta	Spontaneous expulsions.				
	Assisted expulsion				
	Manual removal				
7. Total duration of labor					
8. Duration of each stage of labor:	**First Stage**	**Second Stage**	**Third Stage**		
Any sign of post-partum hemorrhage	If yes please specify ….				

Neonatal outcome				
The newborn born is	Alive.			
	Asphyxiated			
	Still birth			
APGAR score at 1 minute after birth	0-3.			
	4-6.			
	7-10			
APGAR score at 5 minutes after birth	0-3			
	4-6.			
	7-10.			

Presence of any complications/ birth injury	Caput succedaneum			
	Cephalo Hematoma			
	Minor scalp injury			
	Any other injuries			

SECTION 2 - PART IV

CHILD BIRTH EXPERIENCE QUESTIONNAIRE (CEQ)

(Instructions: please listen to the statements regarding your child birth experiencesand give your opinion)

1. Did your labor and childbirth went as you expected

Totally Agree	Mostly Agree	Mostly disagree	Totally disagree
☐	☐	☐	☐

2. Did you feel strong during your labor and childbirth

Totally Agree	Mostly Agree	Mostly disagree	Totally disagree
☐	☐	☐	☐

3. Did you feel scared during labor and childbirth (reversed scored)

Totally Agree	Mostly Agree	Mostly disagree	Totally disagree
☐	☐	☐	☐

4. Did you feel capable during your labor and childbirth

Totally Agree	Mostly Agree	Mostly disagree	Totally disagree
☐	☐	☐	☐

5. Did you feel tired during your labor and childbirth(reverse scored)

Totally Agree ☐ Mostly Agree ☐ Mostly disagree ☐ Totally disagree ☐

6. Did you feel happy during your labor and childbirth

Totally Agree ☐ Mostly Agree ☐ Mostly disagree ☐ Totally disagree ☐

7. Did you have positive memories from child birth

Totally Agree ☐ Mostly Agree ☐ Mostly disagree ☐ Totally disagree ☐

8. Did you have negative memories from child birth(reverse scored)

Totally Agree ☐ Mostly Agree ☐ Mostly disagree ☐ Totally disagree ☐

9. Did you feel depressed due to certain memories of child birth(reverse scored)

Totally Agree ☐ Mostly Agree ☐ Mostly disagree ☐ Totally disagree ☐

10. Did you feel your nurse spent enough time on you

Totally Agree Mostly Agree Mostly disagree Totally disagree

☐ ☐ ☐ ☐

11. Did you feel that your nurse kept you informed about what was happening during labor and birth

Totally Agree Mostly Agree Mostly disagree Totally disagree

☐ ☐ ☐ ☐

12. Did you feel that your nurse understood your needs

Totally Agree Mostly Agree Mostly disagree Totally disagree

☐ ☐ ☐ ☐

13. Did you feel very well cared for by your nurse

Totally Agree Mostly Agree Mostly disagree Totally disagree

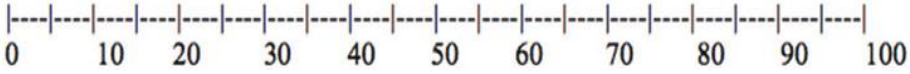
☐ ☐ ☐ ☐

14. Did you feel that you handled the situation well

Totally Agree Mostly Agree Mostly disagree Totally disagree

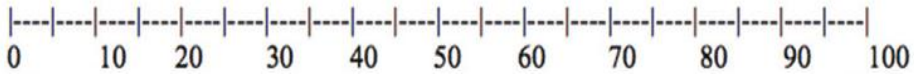
☐ ☐ ☐ ☐

15. As a whole , how painful did you feel the child birth was?(reversed scored)



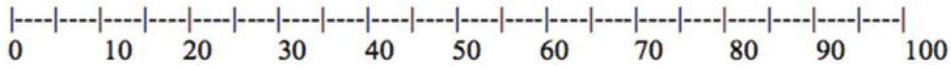
No pain Worst Imaginable Pain

16. As a whole , how much control did you feel you had during child birth?



No Control Complete control

17. As a whole , how much satisfaction did you feel after child birth?



Not at all Fully satisfied

Annexure-5
DATA COLLECTION TOOL (Hindi)

खंड ए: डेटा संग्रह के लिए स्क्रीनिंग टूल

सीरीयल नम्बर .....

मूल्यांकन की तिथि:

पता:

मोबाइल नंबर:

अनुदेश: उचित उत्तर पर घेरा लगायें

1.	क्या महिलाएं पहली बार गर्भवती हैं (प्राइमिग्रेविडा)	हाँ	नहीं
2.	क्या गर्भवती महिला की उम्र 18 वर्ष से अधिक है?	हाँ	नहीं
3.	क्या आप हिंदी, अंग्रेजी या दोनों समझते हैं?	हाँ	नहीं
4.	क्या ग्राहक भाग लेने के लिए इच्छुक है या सूचित सहमति दे रहा है?	हाँ	नहीं
5.	क्या गर्भवती महिला गर्भधारण की अवधि 35 सप्ताह से 36+6 दिन के बीच है	हाँ	नहीं
6.	क्या गर्भवती महिलाओं के पास स्मार्ट फोन है और वे जानती हैं कि इसका इस्तेमाल कैसे करते है ?	हाँ	नहीं
7.	क्या गर्भवती महिलाओं को कोई चिकित्सीय या सर्जिकल जटिलताएँ नहीं है जो गर्भावस्था को जटिल बना सकता है केस शीट के अनुसार	हाँ	नहीं
8.	क्या गर्भवती महिला केस शीट के अनुसार मानसिक रूप से स्वस्थ है?	हाँ	नहीं
9.	क्या गर्भवती महिलाएं प्रसव संबंधी कोई तैयारी कक्षा ले रही हैं?	हाँ	नहीं

अनुमान: शामिल करें/बहिष्कृत करें

खंड बी - भाग I

सामाजिक-जनसांख्यिकीय परिवर्तनीय प्रदर्शन

निर्देश :

• कृपया ध्यानपूर्वक पढ़ें और दिए गए विकल्प के सामने ✓ का निशान लगाएं

प्रतिभागी पहचान संख्या .....

1. **आयु .....**

2. **शिक्षा (कुप्पुस्वामी का पैमाना)**

a) पेशा या सम्मान

b) स्नातक

c) इटरमीडिएट या डिप्लोमा

d) हाई स्कूल प्रमाणपत्र

e) मिडिल स्कूल प्रमाणपत्र

f) प्राथमिक विद्यालय प्रमाणपत्र

g) अनपढ़

3. **व्यवसाय**

a) गृह निर्माता

b) पेशेवर

c) स्व-रोज़गार

d) घर से काम

4. निवास

a) ग्रामीण

b) शहरी

5. धर्म

a) हिंदू धर्म

b) ईसाई धर्म

c) इस्लाम

d) अन्य

6. परिवार का प्रकार

a) एकल परिवार

b) संयुक्त परिवार

7. आपका सामाजिक समर्थन कौन है?

a) पति

b) माता-पिता

c) ससुराल

d) रिश्तेदार

e) कोई अन्य, यदि हां तो बताएं

8. क्या आपको धूम्रपान की आदत है

a) हाँ

b) नहीं

9. क्या आपकी गर्भावस्था नियोजित है?

a) हाँ

b) नहीं

खंड 2 - भाग 4
शिशु जन्म अनुभव प्रश्नावली (सीईक्यू)

निर्देश: कृपया अपने बच्चे के जन्म के अनुभवों के संबंध में कथन सुनें और अपनी राय दें)

1. क्या आपका प्रसव और बच्चे का जन्म आपकी अपेक्षा के अनुरूप हुआ?

पूर्णतः सहमत	अधिकतर सहमत	अधिकतर असहमत	पूर्णतया असहमत
☐	☐	☐	☐

2. क्या आपको प्रसव और के बच्चे का जन्म दौरान मजबूत महसूस हुआ?

पूर्णतः सहमत	अधिकतर सहमत	अधिकतर असहमत	पूर्णतया असहमत
☐	☐	☐	☐

3. क्या आपको प्रसव और बच्चे का जन्म के दौरान डर महसूस हुआ?

पूर्णतः सहमत	अधिकतर सहमत	अधिकतर असहमत	पूर्णतया असहमत
☐	☐	☐	☐

4. क्या आप प्रसव और बच्चे का जन्म के दौरान सक्षम महसूस करती थीं?

पूर्णतः सहमत	अधिकतर सहमत	अधिकतर असहमत	पूर्णतया असहमत

☐	☐	☐	☐

5. क्या आपको प्रसव और बच्चे का जन्म के दौरान थकान महसूस हुई?

पूर्णतः सहमत	अधिकतर सहमत	अधिकतर असहमत	पूर्णतया असहमत
☐	☐	☐	☐

6. क्या आपको प्रसव और के दौरान खुशी महसूस हुई?

पूर्णतः सहमत	अधिकतर सहमत	अधिकतर असहमत	पूर्णतया असहमत
☐	☐	☐	☐

7. क्या बच्चे के जन्म से जुड़ी आपकी कोई सकारात्मक यादें हैं?

पूर्णतः सहमत	अधिकतर सहमत	अधिकतर असहमत	पूर्णतया असहमत
☐	☐	☐	☐

8.क्या आपको बच्चे के जन्म से जुड़ी नकारात्मक यादें हैं?

पूर्णतः सहमत	अधिकतर सहमत	अधिकतर असहमत	पूर्णतया असहमत
☐	☐	☐	☐

9. क्या आप बच्चे के जन्म की कुछ यादों के कारण उदास महसूस करते हैं?

पूर्णतः सहमत	अधिकतर सहमत	अधिकतर असहमत	पूर्णतया असहमत

☐	☐	☐	☐

10. क्या आपको लगा कि आपकी नर्स ने आप पर पर्याप्त समय बिताया है

पूर्णतः सहमत	अधिकतर सहमत	अधिकतर असहमत	पूर्णतया असहमत
☐	☐	☐	☐

11. क्या आपको महसूस हुआ कि आपकी नर्स आपको प्रसव और जन्म के दौरान क्या हो रहा था, इसकी जानकारी देती थी

पूर्णतः सहमत	अधिकतर सहमत	अधिकतर असहमत	पूर्णतया असहमत
☐	☐	☐	☐

12. क्या आपको लगा कि आपकी नर्स आपकी ज़रूरतों को समझती है

पूर्णतः सहमत	अधिकतर सहमत	अधिकतर असहमत	पूर्णतया असहमत
☐	☐	☐	☐

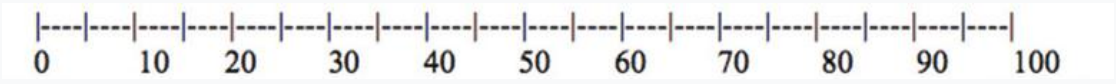
13. क्या आपको अपनी नर्स द्वारा बहुत अच्छी देखभाल महसूस हुई?

पूर्णतः सहमत	अधिकतर सहमत	अधिकतर असहमत	पूर्णतया असहमत
☐	☐	☐	☐

14. क्या आपको लगा कि आपने स्थिति को अच्छे से संभाला है?

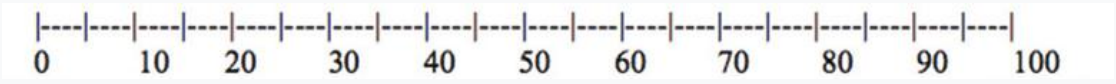
पूर्णतः सहमत	अधिकतर सहमत	अधिकतर असहमत	पूर्णतया असहमत
☐	☐	☐	☐

15. कुल मिलाकर, आपको बच्चे का जन्म कितना दर्दनाक लगा?



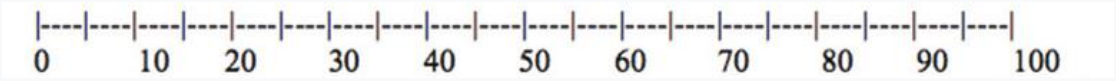
कोई दर्द नहीं सबसे खराब कल्पनाशील दर्द

16. कुल मिलाकर, बच्चे के जन्म के दौरान आपको कितना नियंत्रण महसूस हुआ?



कोई नियंत्रण नहीं पूर्ण नियंत्रण

17. कुल मिलाकर, बच्चे के जन्म के बाद आपको कितनी संतुष्टि महसूस हुई?



बिल्कुल नहीं पूरी तरह से संतुष्ट

Annexure- 6

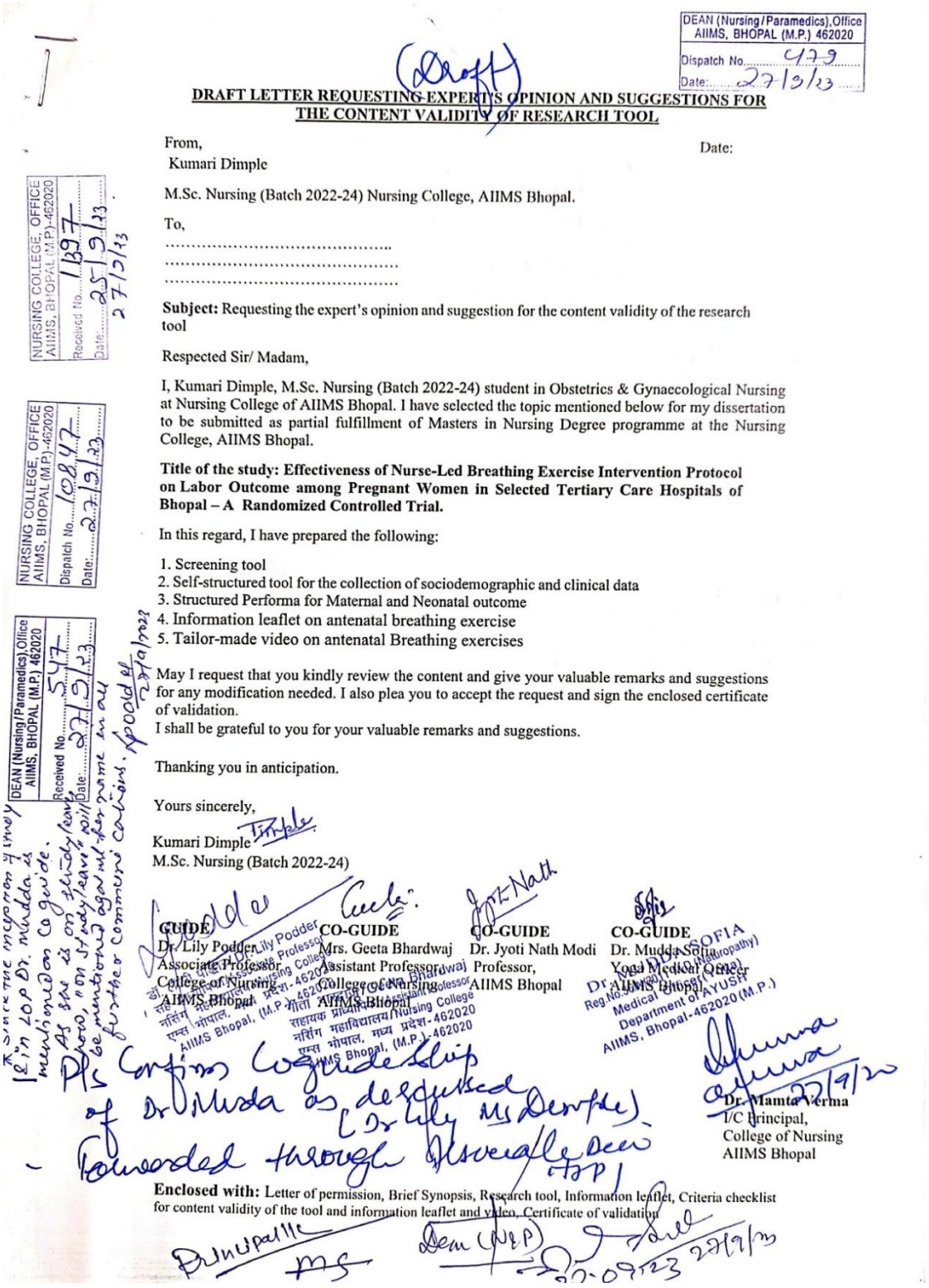
LIST OF EXPERTS FOR TOOL VALIDATION

S.No.	Name of the Expert	Designation and institution
Expert 1	Mrs. Naseema Shafqat	Assistant Professor, College of Nursing AIIMS Bhopal
Expert 2	Dr. K.Pushpalatha	Additional Professor & HOD Obstetrics and Gynaecology Department AIIMS Bhopal
Expert 3	Dr. Ajay Haldar	Associate Professor Obstetrics and Gynaecology Department AIIMS Bhopal
Expert 4	Dr. Arun Kumar Dora	Associate Professor Obstetrics and Gynaecology Department AIIMS Bhopal
Expert 5	Dr. Shweta Patel	Assistant Professor Obstetrics and Gynaecology Department AIIMS Bhopal
Expert 6	Dr. Bharti Singh	Assistant Professor Obstetrics and Gynaecology Department AIIMS Bhopal
Expert 7	Ms. Nivedita	Assistant nursing superintendent AIIMS Bhopal

Expert 8	Sunita mam	Assistant nursing superintendent AIIMS Bhopal
Expert 9	Khushboo	Assistant nursing superintendent AIIMS Bhopal
Expert 10	Himanshu Vyas	Associate Professor ,college of Nursing AIIMS Jodhpur
Expert 11	Dr. Prasuna Jelly	Associate Professor ,college of Nursing AIIMS Rishikesh
Expert 12	Ms. Manita Dalal	Tutor ,college of Nursing AIIMS Delhi
Expert 13	Dharitri Swain	Assistant Professor, college of Nursing AIIMS Bhubaneswar
Expert 14	Mrs. Vahitha S	college of Nursing AIIMS Raipur
Expert 15	D Koteswaramma	college of Nursing AIIMS Patna
Expert 16	Mrs. Anju Verma	Associate Professor College of Nursing SGPGIMS
Expert 17	Mrs. Niza Subramaniyam	Assistant Professor College of Nursing BHU
Expert 18	Mrs. Anitha Moncy	Assistant Professor College of Nursing BHU
Expert 19	Dr. Seema Rani Chopra	Associate Professor GCON,Surat
Expert 20	Dr Sushmitha Ramona Karkada	Assistant professor, Manipal College of Nursing
Expert 21	Dr. Kirandeep Kaur	Department of Obstetrics and Gynaecology, PGIMER Chandigarh
Expert 22	Dr. Ankita	Department of PMR AIIMS Bhopal
Expert 23	Dr. Shagufta Parveen	Masters of physical therepy (women Health, Child Birth Educator)
Expert 24	Dr. Renu	Associate professor St. Stephen Hospital, college of Nursing
Expert 25	Ms. Shobitha	Nursing Officer AIIMS Bhopal

Annexure- 7

Letter for validation of tool



DEAN (Nursing/Paramedics), Office
AIIMS, BHOPAL (M.P.) 462020
Dispatch No. 479
Date: 27/9/23

DRAFT LETTER REQUESTING EXPERTS OPINION AND SUGGESTIONS FOR THE CONTENT VALIDITY OF RESEARCH TOOL

From,
Kumari Dimple

Date:

M.Sc. Nursing (Batch 2022-24) Nursing College, AIIMS Bhopal.

To,
.....
.....
.....

NURSING COLLEGE, OFFICE
AIIMS, BHOPAL (M.P.)-462020
Received No. 1397
Date: 25/9/23
27/9/23

NURSING COLLEGE, OFFICE
AIIMS, BHOPAL (M.P.)-462020
Dispatch No. 10847
Date: 27.9.23

DEAN (Nursing/Paramedics), Office
AIIMS, BHOPAL (M.P.) 462020
Received No. 547
Date: 27/9/23

Subject: Requesting the expert's opinion and suggestion for the content validity of the research tool

Respected Sir/ Madam,

I, Kumari Dimple, M.Sc. Nursing (Batch 2022-24) student in Obstetrics & Gynaecological Nursing at Nursing College of AIIMS Bhopal. I have selected the topic mentioned below for my dissertation to be submitted as partial fulfillment of Masters in Nursing Degree programme at the Nursing College, AIIMS Bhopal.

Title of the study: Effectiveness of Nurse-Led Breathing Exercise Intervention Protocol on Labor Outcome among Pregnant Women in Selected Tertiary Care Hospitals of Bhopal – A Randomized Controlled Trial.

In this regard, I have prepared the following:

1. Screening tool
2. Self-structured tool for the collection of sociodemographic and clinical data
3. Structured Performa for Maternal and Neonatal outcome
4. Information leaflet on antenatal breathing exercise
5. Tailor-made video on antenatal Breathing exercises

May I request that you kindly review the content and give your valuable remarks and suggestions for any modification needed. I also plea you to accept the request and sign the enclosed certificate of validation.
I shall be grateful to you for your valuable remarks and suggestions.

Thanking you in anticipation.

Yours sincerely,

Kumari Dimple
M.Sc. Nursing (Batch 2022-24)

GUIDE	CO-GUIDE	CO-GUIDE	CO-GUIDE
Dr. Lily Podder	Mrs. Geeta Bhardwaj	Dr. Jyoti Nath Modi	Dr. Mudda Sofia
Associate Professor,	Assistant Professor,	Professor,	Yoga Medical Officer (Naturopathy)
College of Nursing,	College of Nursing,	AIIMS Bhopal	AIIMS Bhopal
AIIMS Bhopal	AIIMS Bhopal		

Dr. Mamta Verma
I/C Principal,
College of Nursing
AIIMS Bhopal

Enclosed with: Letter of permission, Brief Synopsis, Research tool, Information leaflet, Criteria checklist for content validity of the tool and information leaflet and video, Certificate of validation

Annexure- 8

Criteria checklist for validation of tool

CRITERIA CHECKLIST FOR THE VALIDATION OF THE TOOL

Section 1 : Screening Tool

The tool contains 9 items regarding screening of participants . We need your expert judgement on degree of relevancy of each item to the measured domains. If there are any suggestions, please mention in the remark column.

s.no.	Item number	Highly relevant 4	Quite relevant 3	Somewhat relevant 2	Not relevant 1	Remarks
1.	Is Women pregnant for the first time (Primigravida)					
2.	Is Pregnant women above the age of 18 years					
3.	Whether the client understand Hindi, English or both?					
4.	Whether the client is willing to participate or giving informed consent?					
5.	Is Pregnant women between 34 week- 36+6 days period of gestation					
6.	Is Pregnant women have smart phone and know how to use it					
7.	Is patient having any medical & surgical					

	complication which might complicate the pregnancy as per case sheet					
8.	Is Pregnant women is mentally sound as per case sheet					

Section 2 -Part A : Demographic data

The tool contains 9 items regarding demographic data. We need your expert judgement on degree of relevancy of each item to the measured domains. If there are any suggestions, please mention in the remark column.

s.no.	Item number	Highly relevant 4	Quite relevant 3	Somewhat relevant 2	Not relevant 1	Remarks
1.	**Age**					
2.	**Education** h) Profession or Honours i) Graduate j) Intermediate or Diploma k) High School Certificate l) Middle school Certificate m) Primary school Certificate n) Illiterate					
3.	**Occupation** e) Home maker f) Professional g) Self employed h) Work from home					
4.	**Residence** a) Rural b) Urban					
5.	**Religion** e) Hinduism f) Christianity g) Islam					

	h) Others					
6.	**Type of family** c) Nuclear d) Joint					
7.	**Social support** f) Husband g) Parents h) In laws i) Relatives j) Any other , if yes then specify					
8.	**Smoking Habit** c) Yes d) No					
9.	**Pregnancy planned** c) Yes d) No					

Section 2 -Part B : clinical sheet Performa

The tool contains 5 items regarding clinical data. We need your expert judgement on degree of relevancy of each item to the measured domains. If there are any suggestions, please mention in the remark column.

s.no.	Item number	Highly relevant 4	Quite relevant 3	Somewhat relevant 2	Not relevant 1	Remarks
1.	LMP					
2.	EDD					
3.	Period of gestation					
4.	Any past medical and					

	surgical history					
5.	Any medical disorder happen during pregnancy					

Section 3 -Part A : Maternal Outcome Performa

The tool contains 9 items regarding maternal outcome . We need your expert judgement on degree of relevancy of each item to the measured domains. If there are any suggestions, please mention in the remark column.

s.no.	Item number	Highly relevant 4	Quite relevant 3	Somewhat relevant 2	Not relevant 1	Remarks
1.	**POG at onset of true labor**					
2.	**Onset of labor** • Spontaneous • Induced					
3.	**Nature of progress of labour** • Progressed Spontaneously • Augmented by any method					
4.	**Mode of delivery** • Vaginal delivery • Instrumental delivery (forceps, vacuum) • Emergency LSCS					

5.	**Nature of vaginal delivery** • Normal vaginal delivery with episiotomy without laceration and tear. • Normal vaginal delivery with episiotomy and laceration. • Normal vaginal delivery with episiotomy and tear. • Normal vaginal delivery without episiotomy					
6.	**Nature of expulsion of placenta** • Spontaneous expulsions. • Assisted expulsion • Manual removal					
7.	**Total duration of labour**					
8.	**Duration of each stage of labour**					
9.	**Any sign of post-partum hemorrhage**					

Section 3 -Part B : Neonatal Outcome Performa

The tool contains 5 items regarding neonatal outcome . We need your expert judgement on degree of relevancy of each item to the measured domains. If there are any suggestions, please mention in the remark column.

s.no.	Item number	Highly relevant 4	Quite relevant 3	Somewhat relevant 2	Not relevant 1	Remarks
1.	The newborn is born • Alive • Asphyxiated • Still birth					
2.	The newborn cried immediately after birth					
3.	APGAR score at 1 minute after birth • 0-3 • 4-6 • 7-10					
4.	APGAR score at 5 minutes after birth • 0-3 • 4-6 • 7-10					
5.	Presence of any complications/ birth injury • Caput succedanum • Cephalon hematoma • Minor scalp injury					

	• Any other injury					

Annexure-9

Certificate of validation

This is to certify that the tool prepared by Kumari Dimple , M.Sc. Nursing 2022 batch student, Nursing college, AIIMS Bhopal, to be used in her study titled "**Effectiveness of nurse-led breathing exercise intervention Protocol on labor outcome among pregnant women in selected tertiary care hospitals of Bhopal – A Randomized Controlled Trial**" has been validated by me and is found to be **valid/ not valid.**

Overall Remark-

Signature:

Name of the expert:

Designation:

Name of the Institution:

Official seal:

Date:

Place:

Annexure-10

Certificate of language validation

CERTIFICATE OF TRANSLATION

TO WHOM IT MAY CONCERN

This is to certify that Ms. Kumari Dimple, (Batch 2022-2024) M.Sc. Obstetrics & Gynecological Nursing student of Nursing College, AIIMS Bhopal is conducting research on topic **"Effectiveness of Nurse Led Breathing Exercise Intervention Protocol on Labor Outcome among pregnant women in selected tertiary care hospitals of Bhopal – A Randomized Controlled Trial."** The Hindi version of Participant Information Sheet, Participant Informed Consent Form, Screening Tool, Demographic tool, Child experience questionnaire, Information leaflet on Breathing Exercises for this study is a true andaccurate translation of the English version and is valid to collect data for research.

Seal & Signature: ..... Dr. Bhawana Pandey
प्राध्यापक
शासकीय म.ल.ब. कन्या स्वशासी स्नातकोत्तर महाविद्यालय भोपाल (म.प्र.)

Name of the language expert: ..... Dr. Bhawana Pandey

Qualification: M.A PhD

Designation: Professor

Name of the institute: Govt. M.L.B college Bhopal.

Date: 27.9.23

Place: Bhopal

Annexure-10

Certificate of language validation

CERTIFICATE OF TRANSLATION

TO WHOM IT MAY CONCERN

This is to certify that Kumari Dimple,(Batch 2022-2024) M.Sc. Obstetrics & Gynecological Nursing student of Nursing College, AIIMS Bhopal is conducting research on topic **"Effectiveness of Nurse Led Breathing Exercise Intervention Protocol on Labor Outcome among pregnant women in selected tertiary care hospitals of Bhopal – A Randomized Controlled Trial."** The English version of Participant Information Sheet, Participant Informed Consent form ,Screening Tool, Demographic tool, Child experience questionnaire, content of Information leaflet on Breathing Exercises and for this study is a true and accurate translation of the Hindi version and is valid to collect data for research.

Seal & Signature: ..... Dr. Bhawna Pandey

Name of the language expert: ..... Dr. Bhawna Pandey
शासकीय म.वि.वा. कन्या स्नातकोत्तर स्वशासी महाविद्यालय भोपाल (म.प्र.)

Qualification: ..... MA. PhD

Designation: ..... Professor

Name of the institute: ..... Govt MLB College, Bhopal

Date: 27.9.23

Place: ..... Bhopal

Annexure- 11

Certificate of workshop on antenatal and postnatal exercises

CIN U85110UP2017NPL093973 ISO CERTIFIED 9001 : 2015 http://www.ihfafitness.com | e-mail: edu@ihfafitness.com

International Health and Fitness Association

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IHFA

INTERNATIONAL HEALTH AND FITNESS ASSOCIATION

Batch # 48

Certificate # 9477

Workshop Date: 29th, 30th April 2023

Date of issue: 29th April 2023

Course Hours 16

Training Site: Bangalore, India

HEREBY CERTIFIED THAT

Kumari Dimple

Registration ID # IHFA2319137785

Bangalore, Karnataka, India

HAS SUCCESSFULLY COMPLETED

THE REQUIREMENTS OF THE CURRICULUM AND

IS HEREBY AWARDED THIS CERTIFICATE FOR THE COURSE OF

Certified Antenatal Postnatal Exercise Specialist (CAPES)™

Course Approved for 1.6 CHEs (Continuing Health Education Units)

CHANNEL PARTNER : EDUCORD INTERNATIONAL PVT. LTD.

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DR.VIPIN KUMAR(PT)

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MPT (Gynae

Director IHFA (Women's Health

Office:

Mandir Marg Mahavir Enclave , New Delhi 110045 India

This document can be verify on www.ihfafitness.com | info@ihfafitness.com

Associate Office

NCCPT , 3481, Old Cadnejo Rd

Annexure-12

Content area for video regarding antenatal breathing exercises

S.No.	Content	Time (minute & second)	References
	Introduction, purpose of the video and meaning of labor	00 to 1	1. Elizabeth, Marie. Midwifery for Nurses. India, CBS Publishers & Distributors, 2018. 2. Dandelion medical animation video
	Importance of antenatal breathing exercise during labor	1.01 to 1.54	1. Lieberman, Adrienne B.. Easing Labor Pain: The Complete Guide to a More Comfortable and Rewarding Birth. United States, Harvard Common Press, 1992. 2. Pandit, Nutan, and Lakhanpal, Nutun. Pregnancy. India, Rupa & Company, 1991.
	Instruction before performing breathing exercises	1.55 to 2.56	1. Lieberman, Adrienne B.. Easing Labor Pain: The Complete Guide to a More Comfortable and Rewarding Birth. United States, Harvard Common Press, 1992. 2. Pandit, Nutan, and Lakhanpal, Nutun. Pregnancy. India, Rupa & Company, 1991.
	Steps to perform Various antenatal breathing exercise	2.56 to 8.10	1. Pandit, Nutan, and Lakhanpal, Nutun. Pregnancy. India, Rupa & Company, 1991. 2. Lieberman, Adrienne B.. Easing Labor Pain: The Complete Guide to a More Comfortable and Rewarding Birth. United States, Harvard Common Press, 1992. 3. Davidson, Michele R. Olds' Maternal-Newborn Nursing & Women's Health across the Lifespan. Boston: Pearson, 2012. 4. Pillitteri, Adele. Maternal & Child Health Nursing: Care of the Childbearing & Childrearing Family. United Kingdom, Wolters Kluwer Health/Lippincott Williams & Wilkins, 2010.
	Summary and conclusion	8.11 to 8.50	

Annexure-13

Certificate of validation for tailor made video

This is to certify that the tailor made video on antenatal Breathing exercises prepared by Kumari Dimple , M.Sc. Nursing 2022 batch student, Nursing college, AIIMS Bhopal, to be used in her study titled "**Effectiveness of nurse-led breathing exercise intervention Protocol on labor outcome among pregnant women in selected tertiary care hospitals of Bhopal – A Randomized Controlled Trial**" has been validated by me and is found to be **valid/ not valid.**

Overall Remark-

Signature:

Name of the expert:

Designation:

Name of the Institution:

Official seal:

Date:

Place:

Annexure-14

Certificate of technical validation for tailor made video

This is to certify that the visual clarity and audibility of tailor made video on antenatal Breathing exercises prepared by Kumari Dimple , M.Sc. Nursing 2022 batch student, Nursing college, AIIMS Bhopal, to prepare pregnant women for labor, is assessed and checked by me and is found to be adequate for display.

Overall Remark-

Signature:

Name of the expert:

Date:

Place:

Annexure-15

Video and photo consent form

Without expectation or other remuneration, now or in the future, I hereby given my consent to Kumari Dimple, M.Sc. Nursing 2022 batch student, Nursing college, AIIMS Bhopal, to use my video in her research study title "**Effectiveness of nurse-led breathing exercise intervention Protocol on labor outcome among pregnant women in selected tertiary care hospitals of Bhopal – A Randomized Controlled Trial**"

The purpose of the using video to prepare pregnant women for labor by using antenatal breathing exercises

Name:_____

Signature: _____

Date: _____

Witness:_____

Annexure-16

Information leaflet on antenatal breathing exercises(English)

ANTENATAL BREATHING EXERCISE

Instruction before initiating breathing exercises

- Before start any breathing exercise find a comfortable position to perform
- Wear comfortable, loose clothing when doing theexercises
- Do the exercise twice a day , 2 sets of breathingexercise protocol each time (morning just after the wake up and night before going to sleep)
- Do not exercise immediately after eating; keep agap of at least ½ hour.
- Relax your body – close your eyes if you're comfortable doing so.
- Loosen any tight clothing that might restrict yourbreathing
- Place your one hand on your chest and other onyour belly.

All images are prepared by Researcher, No copyright

One set of breathing exercise interventionprotocol consist of:

Deep cleansing breath (For 30 second)
↓
Slow paced breathing (For 30 second)
↓
1 Deep cleansing breath
↓
Light and more rapid breath (for 30 second)
↓
1 Deep cleansing breath
↓
Pant blow breath (for 30 second)
↓
Deep cleansing breath (for 30 second)

After 37+ 6 days POG

Deep cleansing breath (For 30 second)
↓
Slow paced breathing (For 30 second)
↓
1 Deep cleansing breath
↓
Light and more rapid breath (for 30 second)
↓
1 Deep cleansing breath
↓
Pant blow breath (for 30 second)
↓
1 Deep cleansing breath
↓
1- Pushing Breath
↓
Deep cleansing breath (for 30 second)

Deep cleansing breath

- Inhale slowly and deeply - set a count ,inhale count of
- then hold your breath- hold for a count of four
- and exhale slowly and completely- exhale for a count of six

Slow paced breathing

- Inhale through your nose on count of four
- Exhale through your mouth on count of six ,exhale likeyou were trying to flicker the flame of a burning candle

Light and more rapid breath

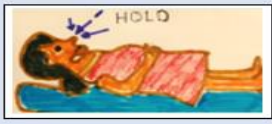
- The rhythm for the breath counted as one and two andone and two ……
- Inhale through the nose /mouth on and
- Exhaling on number one , two through the mouth

Pant blow breath

- Inhale through the mouth/nose quick inhale "hee hee" either 3 , 2 times
- For ex. Hee hee hoo (quick inhale on hee and quick exhaleon hoo.)

Pushing Breath

- Either lie down using 2 pillows under your head orsit your legs stretched in front of you.
- Perform 1st slow paced breathing, 2nd slow pacedbreath
- 3rd slow paced breath , after inhaling hold your breath .while holding your breath incline your chin slightly towards you chest.



Annexure-17

COMPLIANCE CHECKLIST

- Participant identification number……
- **INSTRUCTIONS –**

✓ This is the compliance checklist to chart daily breathing exercise done by you.
✓ You have to perform breathing exercises as demonstrated twice daily & chart it in this form against your Period Of Gestation (POG).
✓ Tick the chart only after you complete the entire set of breathing exercise .

Week of gestation	Day from POG	MORNING Tick & time	EVENING Tick & Time	REMARK
35 week	1st day			
	2nd day			
	3rd day			
	4th day			
	5th day			
	6th day			
	7th day			
36 week	1st day			
	2nd day			
	3rd day			
	4th day			
	5th day			
	6th day			
	7th day			
37 week	1st day			
	2nd day			
	3rd day			
	4th day			
	5th day			
	6th day			
	7th day			
38 week	1st day			
	2nd day			
	3rd day			
	4th day			
	5th day			
	6th day			
	7th day			
39 week	1st day			
	2nd day			
	3rd day			
	4th day			
	5th day			
	6th day			
	7th day			
40 Week	1st day			
	2nd day			
	3rd day			
	4th day			
	5th day			
	6th day			
	7th day			

Annexure-18

Participant Information Sheet (English)

1. **Study Title:** Effectiveness of nurse-led breathing exercise intervention Protocol on labor outcome among pregnant women in selected tertiary care hospitals of Bhopal – A Randomized Controlled Trial.
2. **Principal Investigator**: Kumari Dimple M.Sc. Nursing student Obstetrics & Gynecology (2022-2024)
3. **Guidance**: Dr.Lily Podder Associate Professor College of Nursing AIIMS Bhopal (Guide), Dr. Jyoti Nath Modi Obstetrics & Gynecology Associate Professor AIIMS Bhopal (Co-Guide) & Mrs. Geeta Bhardwaj Assistant professor College of Nursing (Co-Guide) .
4. **Introduction**: Childbirth is the intense and life transforming event in the women & her family . The health and well being of mother and child during pregnancy and childbirth are public health concerns because both of them have special needs which cannot be catered by general health services .

   Although childbirth is a matter of highly medical concern but a now a days lot of emphasis is given in natural birth with minimal intervention ,that's why it is ideal time to advise women on the normal physiological processes of pregnancy and childbirth that would help them to prepared .

   Both childbirth education and non pharmacological intervention help mother to prepared for childbirth but education will only help in building self esteem , self-efficacy but weekly effect on reducing intervention during labor ,when education combined with non pharmacological method it offers remarkable satisfying labor experience with minimum labor intervention .

   There are various non pharmacological techniques are available like relaxation ,positioning ,massage ,breathing etc . But in restricted birthing environment breathing may be only non pharmacological comfort strategy available to women .

   Breathing distracts the focus away from pain and enables mother to be to give birth awake and aware and adjust her breathing level as labor progresses .
5. **Participation – what is included**?

a) Should I participate?
   Participation in this research is completely voluntary.

b) What is expected of me if I join?
   After obtaining informed consent, you will be asked your personal demographic data and clinical data (POG , LMP,EDD, gravida , parity)

You may provide the relevant details asked and cooperate for the breathing intervention by the investigators .

c) How long will my participation in the study last
The duration of participation may last 15-20 minutes During that time investigator will demonstrate and show you a video on the physiology of labor , need of breathing exercise during labor how to perform and will take a demonstration this will be done at 35 weeks and daily 15 minutes twice a day you will continue till the day of labor pain and also continuing throughout the labor

d) Do I have to come separately for this study or will an additional test be necessary
No. You will be called on the same day according to your antenatal visit schedule and no additional test will be asked to do .

e) What are the potential benefits of joining?
Free education and demonstration on breathing exercises will be shown to you that will help you to improve your labor outcome .

f) Potential loss and risk from participating in it.
There is no harm or risk due to participation in this study. .

g) What will happen to the information collected about me?
All information collected will be kept strictly confidential. Access to data will be provided only to individuals permitted by law if deemed necessary.

h) What happens if I change my mind about participating in this study?
You have the right to change your views at any time during the course of study without any damages orpenalties.

6. Whom should I contact for more information regarding this or if I have any question/doubts in mymind later?
If you want any information you can contact:

i) Dr. Shashank Purwar, Member Secretary, Institution Human Ethics Committee. Contact details: phone -7773010099 and email -ihecpgr@aiimsbhopal.edu.in

ii) Kumari Dimple M.Sc. Nursing student Obstetrics & Gynecology , Principal investigator College of Nursing AIIMS Bhopal. Contact details: phone- 6266092298 , EMAIL – dimplesingh83252@gmail.com

Annexure-19
Participant Information Sheet (Hindi)

1. अध्ययन शीर्षक:
   भोपाल के चयनित तृतीयक देखभाल अस्पतालों में गर्भवती महिलाओं के बीच श्रम परिणाम पर नर्स के नेतृत्व वाले श्वास व्यायाम हस्तक्षेप प्रोटोकॉल की प्रभावशीलता - ए आरएंडोमाइज्ड सीऑनट्रॉल टीरियाल।

2. प्रधान अन्वेषक:
   कुमारी डिंपल M.Sc नर्सिंग छात्र प्रसूति एवं स्त्री रोग (2022-2024)

3. मार्गदर्शन:
   डॉ लिली पोद्दार, एसोसिएट प्रोफेसर, नर्सिंग कॉलेज, एम्स भोपाल (गाइड), डॉ ज्योति नाथ मोदी, प्रसूति एवं स्त्री रोग एसोसिएट प्रोफेसर, एम्स भोपाल (सह-गाइड) और श्रीमती गीता भारद्वाज सहायक प्रोफेसर कॉलेज ऑफ नर्सिंग (सह-गाइड)।

4. परिचय:
   प्रसव महिलाओं और उसके परिवार में तीव्र और जीवन बदलने वाली घटना है। गर्भावस्था और प्रसव के दौरान मां और बच्चे का स्वास्थ्य और कल्याण सार्वजनिक स्वास्थ्य चिंताएं हैं क्योंकि दोनों की विशेष आवश्यकताएं हैं जिन्हें सामान्य स्वास्थ्य सेवाओं द्वारा पूरा नहीं किया जा सकता है।

   यद्यपि प्रसव अत्यधिक चिकित्सा चिंता का विषय है, लेकिन अब न्यूनतम हस्तक्षेप के साथ प्राकृतिक जन्म में बहुत जोर दिया जाता है, यही कारण है कि गर्भावस्था और प्रसव की सामान्य शारीरिक प्रक्रियाओं पर महिलाओं को सलाह देने का यह आदर्श समय है जो उन्हें तैयार करने में मदद करेगा।

   प्रसव शिक्षा और गैर फार्माकोलओगिकल हस्तक्षेप दोनों मां को प्रसव के लिए तैयार करने में मदद करते हैं, लेकिन शिक्षा केवल आत्मसम्मान, आत्म-प्रभावकारिता के निर्माण में मदद करेगी, लेकिन श्रम के दौरान हस्तक्षेप को कम करने पर साप्ताहिक प्रभाव, जब शिक्षा गैर-फार्मालॉजिकल विधि के साथ संयुक्त होती है तो यह न्यूनतम श्रम हस्तक्षेप के साथ उल्लेखनीय संतोषजनक श्रम अनुभव प्रदान करती है।

   विभिन्न गैर औषधीय तकनीकें उपलब्ध हैं जैसे विश्राम, स्थिति, मालिश, श्वास आदि। लेकिन सीमित जन्म के माहौल में सांस लेना महिलाओं के लिए उपलब्ध केवल गैर औषधीय आराम रणनीति हो सकती है।

   श्वास से ध्यान दर्द से दूर हो जाता है और माँ को बच्चे को जागृत और जागरूक करने में सक्षम बनाता है और प्रसव के बढ़ने पर अपने श्वास स्तर को समायोजित करता है।

5. भागीदारी - क्या शामिल है?

   a) क्या मुझे भाग लेना चाहिए?
   इस शोध में भागीदारी पूरी तरह से स्वैच्छिक है।
   b) अगर मैं शामिल होता हूं तो मुझसे क्या उम्मीद की जाती है?
   सूचित सहमति प्राप्त करने के बाद, आपसे आपके व्यक्तिगत जनसांख्यिकीय डेटा और नैदानिक डेटा (पीओजी, एलएमपी, ईडीडी, ग्रेविडा, समता) पूछा जाएगा।
   आप पूछे गए प्रासंगिक विवरण प्रदान कर सकते हैं और जांचकर्ताओं द्वारा श्वास हस्तक्षेप के लिए सहयोग कर सकते हैं।

   c) अध्ययन में मेरी भागीदारी कब तक चलेउस
   समय के दौरान अन्वेषक आपको प्रसव के शरीर विज्ञान पर एक वीडियो दिखाएगा और दिखाएगा कि प्रसव के दौरान श्वास व्यायाम की आवश्यकता कैसे प्रदर्शन करना है और एक प्रदर्शन लेगा यह

35 सप्ताह और दिन में दो बार दैनिक 15 मिनट में किया जाएगा, आप प्रसव पीड़ा के दिन तक जारी रखेंगे और पूरे प्रसव के दौरान भी जारी रहेंगे।

d) क्या मुझे इस अध्ययन के लिए अलग से आना होगा या एक अतिरिक्त परीक्षण आवश्यक होगा

नहीं। आपको आपके प्रसवपूर्व यात्रा कार्यक्रम के अनुसार उसी दिन बुलाया जाएगा और कोई अतिरिक्त परीक्षण करने के लिए नहीं कहा जाएगा।

a) शामिल होने के संभावित लाभ क्या हैं?

श्वास अभ्यास पर मुफ्त शिक्षा और प्रदर्शन आपको दिखाया जाएगा जो आपको अपने श्रम परिणाम को बेहतर बनाने में मदद करेगा। .

b) इसमें भाग लेने से संभावित नुकसान और जोखिम।

इस अध्ययन में भाग लेने के कारण कोई नुकसान या जोखिम नहीं है।

c) मेरे बारे में एकत्र की गई जानकारी का क्या होगा?

एकत्र की गई सभी जानकारी को सख्ती से गोपनीय रखा जाएगा। डेटा तक पहुंच केवल उन व्यक्तियों को प्रदान की जाएगी जिन्हें आवश्यक समझा जाता है।

d) क्या होगा अगर मैं इस अध्ययन में भाग लेने के बारे में अपना मन बदलता हूं?

आपको बिना किसी नुकसान या दंड के अध्ययन के दौरान किसी भी समय अपने विचारों को बदलने का अधिकार है।

इस बारे में अधिक जानकारी के लिए मुझे किससे संपर्क करना चाहिए या यदि मेरे मन में बाद में कोई प्रश्न /संदेह है?

यदि आप कोई जानकारी चाहते हैं तो आप संपर्क कर सकते हैं:

डॉ शशांक पुरवार, सदस्य सचिव, संस्था मानव आचार समिति। संपर्क विवरण: फोन - 7773010099 और ईमेल -ihecpgr@aiimsbhopal.edu.in

डॉ ममता वर्मा, प्राचार्य नर्सिंग कॉलेज, एम्स भोपाल। संपर्क विवरण: फोन- +919981540519, ईमेल- principal.nursing@aiimsbhopal.edu.in

Annexure-20
Participant Consent Form(English/ Hindi)

इस अध्ययन के लिए प्रतिभागी का पहचान नंबरः .....
Participant Identification Number for this Study .....

अध्ययन शीर्षक: भोपाल के चयनित तृतीयक देखभाल अस्पतालों में गर्भवती महिलाओं के बीच श्रम परिणाम पर नर्स के नेतृत्व वाले श्वास व्यायाम हस्तक्षेप प्रोटोकॉल की प्रभावशीलता - ए आरएंडोमाइज्ड सीऑनट्रॉल टीरियाल।

Study Title: Effectiveness of nurse-led breathing exercise intervention Protocol on labor outcome among pregnant women in selected tertiary care hospitals of Bhopal – A Randomized Controlled Trial

शोधकर्ता छात्र का नाम- कुमारी डिंपल M.Sc नर्सिंग छात्र प्रसूति एवं स्त्री रोग (2022-2024)

Principal Investigator: Kumari Dimple M.Sc Nursing student Obstetrics & Gynecology (2022-2024)

मार्गदर्शन: डॉ लिली पोद्दार, एसोसिएट प्रोफेसर, नर्सिंग कॉलेज, एम्स भोपाल (गाइड), डॉ ज्योति नाथ मोदी, प्रसूति एवं स्त्री रोग एसोसिएट प्रोफेसर, एम्स भोपाल (सह-गाइड) और श्रीमती गीता भारद्वाज सहायक प्रोफेसर कॉलेज ऑफ नर्सिंग (सह-गाइड)

Guidance: Dr.Lily Podder, Associate Professor, College of Nursing, AIIMS Bhopal (Guide), Dr. Jyoti Nath Modi , Obstetrics & Gynecology Associate Professor, AIIMS Bhopal (Co-Guide) & Mrs. Geeta Bhardwaj Assistant professor College of Nursing (Co-Guide) .

मैंने दिनांक 14.1.23 के सूचना पत्रक संस्करण II में दिए गए सभी तथ्यों को सावधानीपूर्वक पढ़ लिया है/ मुझे अपनी भाषा में स्पष्ट रूप से विस्तारपूर्वक समझा दिया गया है, और मैंने तथ्यों को पूर्णतः समझ लिया है। मैं पुष्टि करता/ करती हूँ, कि मुझे सवाल पूछने के अवसर प्रदान किए गए।

The contents of the information sheet dated 14 .1 .2023 that was provided have been read carefully by me / explained in detail to me, in a language that I comprehend, and I have fully understood the contents. I confirm that I have had the opportunity to ask questions.

मुझे इस अध्ययन की प्रकृति एवं उद्देश्य और इसके संभावित जोखिमों / लाभों तथा अध्ययन की अनुमानित अवधि एवं अन्य प्रासंगिक जानकारी के बारे में विस्तारपूर्वक समझा दिया गया है। मुझे पता है कि इस अध्ययन में मेरी भागीदारी स्वैच्छिक है तथा मैं इस अध्ययन से किसी भी समय बिना कोई कारण बताए, अपना नाम वापस लेने के लिए स्वतंत्र हूं और नाम वापस लेने पर मेरी कानूनी अधिकारों पर कोई प्रभाव नहीं पड़ेगा।

The nature and purpose of the study and its potential risks/benefits and expected duration of the study, and other relevant details of the study have been explained to me in detail. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal right being affected.

मैं समझता/समझती हूं कि इस अनुसंधान में मेरी भागीदारी से मेरे बारे में एकत्र की गई जानकारी के किसी भी भाग को एम्स के जिम्मेदार व्यक्तियों द्वारा ही देखा जाएगा। मैं इन व्यक्तियों को मेरे रिकॉर्ड प्राप्त करने की अनुमति प्रदान करता/ करती हूँ।

I understand that the information collected about me from my participation in this research and sections of any of my information may be looked at by responsible individuals from AIIMS. I give permission for this individual to have access to my records.

मैं उक्त अध्ययन में भाग लेने के लिए सहमत हूं/I agree to take part in the above study.

_____

(प्रतिभागी के हस्ताक्षर / बांए अंगूठे का निशान) (Signature/Left Thumb Impression)

दिनांक/Date..... स्थान/Place .....

प्रतिभागी का नाम/Name of the participant.....

पिता/पति/पत्नी का नाम /Son/Daughter/Spouse of.....

डाक का पूरा पता /Complete Postal Address .....

अगर अशिक्षित हों / If illiterate.

सूचना पत्र को प्रतिभागी को पढ़ा और समझाया गया है और प्रश्न पूछने का अवसर दिया गया है। मैं पुष्टि करता हूं कि व्यक्ति ने स्वतंत्र रूप से अपनी सहमति दी है ।

The information sheet has been read and explained to the participant and given the opportunity to ask questions. I confirm that the individual has given consent freely.

प्रमाणित किया जाता है कि उक्त सहमति मेरी उपस्थिति में प्राप्त की गई ।

This is to certify that the above consent has been obtained in my presence

_____

छात्र शोधकर्ता के हस्ताक्षर दिनांक.....
स्थान.....

Signature of the student Investigator

Date ..... Place .....

Annexure-21

Master Sheet

PIN	Group	Age	education	occupation	residence	religion	type pf family	social support	Smoking Habit	pregnancy planned	POG at first interaction	POG at onset of labor	The neoborn is born	APGAR at 1 min	APGAR at 5 min	any complication or injury	CEQ Score	CEQ Category
2	1	23	C	A	A	A	B	C	B	B	255	278	A	C	C	A1	56	A
4	1	28	B	A	A	C	B	C	B	B	258	280	A	C	C	B	57	A
6	1	26	A	B	B	B	A	B	B	A	247	276	A	C	C	B	59	A
8	1	26	B	A	A	A	B	A	B	B	254	280	B	C	C	B	50	B
10	1	20	E	A	A	A	B	C	B	B	248	274	A	C	C	B	57	A
12	1	23	C	A	A	A	A	B	B	B	249	277					50	B
14	1	27	A	B	B	A	B	C	B	A	257	279	A	B	C	B	42	B
16	1	24	C	C	B	B	A	B	B	A	253	268	A	C	C	B	54	A
18	1	29	B	A	A	A	B	B	B	A	251	266	A	C	C	B	54	A
20	1	20	C	A	A	A	A	B	B	B	254	277	A	C	C	B	51	A
22	1	28	B	B	A	A	A	B	B	B	253	268	A	C	C	B	51	A
24	1	29	C	A	A	A	B	C	B	B	252	270	A	C	C	B	59	A
26	1	23	D	A	A	A	B	A	B	B	252	281	A	C	C	B	53	A
28	1	33	B	D	A	A	A	C	B	A	258	281	A	C	C	A1	52	A
30	1	31	B	A	B	A	A	A	B	A	256	276	A	C	C	A1	59	A
32	1	22	D	A	B	C	B	A	B	B	258	268	A	C	C	B	52	A
34	1	29	A	A	B	A	A	B	B	B	255	271	A	C	C	B	59	A
36	1	19	E	A	A	C	B	C	B	B	258	285	A	C	C	B	53	A
38	1	21	D	C	A	B	C	B	B	B	253	278	A	C	C	A1	62	A
40	1	19	C	A	A	A	A	B	B	B	257	283	A	C	C	B	63	A
42	1	22	D	A	A	A	B	B	B	B	248	275	A	C	C	A1	60	A
44	1	22	D	A	A	A	B	B	B	B	248	275	A	C	C	A1	60	A
46	1	22	C	A	A	A	B	B	B	B	251	289	B	B	C	B	51	A
48	1	19	E	A	A	A	B	C	B	B	258	279	A	C	C	B	62	A
50	1	21	C	A	A	A	A	C	B	B	252	272	A	C	C	B	56	A

52	1	35	B	B	B	A	B	B	B	A	252	278	A	C	C	B	54	A
54	1	22	D	A	A	A	B	B	B	B	251	265					48	B
56	1	28	A	A	B	A	A	A	B	B	258	274	A	B	C	A1	51	A
58	1	28	B	A	B	A	A	B	B	B	252	281	A	C	C	B	53	A
60	1	26	A	B	A	B	A	C	B	B	251	279	A	C	C	B	57	A
62	1	28	B	A	B	A	A	A	B	A	247	278	A	B	C	A1	51	A
64	1	24	B	A	B	A	A	B	B	B	245	263	A	C	C	B	62	A
66	1	23	C	D	B	A	A	A	B	B	251	276					32	C
68	1	28	D	B	B	A	A	A	B	A	247	265	A	C	C	B	48	B
70	1	21	D	A	A	A	A	A	B	B	245	265	A	C	C	B	50	B
72	1	21	C	C	B	A	B	B	B	A	245	280	A	C	C	B	48	B
74	1	20	C	A	B	C	A	C	B	B	254	276	A	B	C	A1	51	A
76	1	22	E	A	B	A	B	A	B	B	253	283	A	C	C	B	58	A
78	1	26	D	A	A	A	A	A	B	B	258	280					47	B
80	1	28	B	A	B	A	B	C	B	A	254	286	A	B	C	B	61	A
82	1	27	B	A	B	C	B	B	B	A	252	276	A	C	C	B	54	A
84	1	32	B	A	B	A	B	C	B	A	252	280					42	B
86	1	25	B	A	A	C	B	C	B	B	246	279	A	C	C	B	68	A
88	1	22	D	C	B	A	B	B	B	B	248	280	A	C	C	B	49	B
90	1	29	A	A	B	B	A	B	B	A	246	276	A	B	C	A1	51	A
92	1	21	C	A	B	A	A	C	B	B	247	265	A	C	C	B	48	B
94	1	28	A	B	B	A	A	A	B	A	255						51	A
96	1	24	B	C	B	A	A	C	B	B	258	282	A	C	C	B	56	A
98	1	27	B	B	B	B	A	A	B	B	256						44	B
100	1	23	D	A	B	A	A	A	B	B	256	278	A	C	C	B	60	A
1	0	25	D	A	B	A	A	B	B	A	249	274	B	B	B	A1	32	C
3	0	26	D	A	B	A	A	A	B	B	253	281	B	B	A	A1	42	B
5	0	26	D	A	A	A	B	C	B	B	252	279	A	C	C	B	51	A
7	0	29	B	A	A	A	B	C	B	B	257	278	B	B	A	B	32	C
9	0	24	A	A	B	A	A	A	B	A	254	263	A	C	C	B	48	B
11	0	24	D	A	B	A	A	B	B	B	247	276					41	B
13	0	20	F	A	B	A	B	C	B	B	248	265	A	C	C	B	51	A

15	0	21	E	A	B	A	B	C	B	B	247	265	A	B	C	A1	49	B
17	0	23	B	A	A	A	B	C	B	B	248	280	A	C	C	B	45	B
19	0	19	B	C	A	A	B	C	B	B	248	266	A	C	C	B1	38	B
21	0	32	B	C	B	A	B	C	B	A	247	277					50	B
23	0	23	C	A	B	A	A	D	B	B	256	268	A	C	C	B	43	B
25	0	28	B	B	B	B	A	C	B	B	254	270					52	A
27	0	20	D	A	A	C	B	C	B	B	254	281	A	C	C	B	45	B
29	0	22	C	A	A	A	A	D	B	B	250	281	A	B	C	B	41	B
31	0	19	D	A	A	A	B	C	B	B	251	275	A	C	C	A4	35	B
33	0	29	A	A	B	A	A	C	B	B	253	268	A	C	C	B	51	A
35	0	28	B	D	B	A	A	C	B	B	254	273	A	C	C	B	41	B
37	0	20	E	A	A	C	B	B	B	B	256	285	A	C	C	B	49	B
39	0	22	C	A	B	A	A	B	B	B	257	278	A	C	C	B	50	B
41	0	22	C	A	B	A	A	B	B	B	257	283	A	C	C	B	50	B
43	0	23	D	C	A	A	B	B	B	B	256	267	A	C	C	B	42	B
45	0	19	D	A	A	A	B	C	B	B	256	271	A	C	C	A1	38	B
47	0	21	C	A	B	A	B	C	B	B	256	279	A	C	C	B	51	A
49	0	23	F	A	A	A	B	B	B	B	257	276	A	B	C	B	50	B
51	0	20	D	A	A	A	B	C	B	B	258	281	A	C	C	B	48	B
53	0	27	B	B	A	A	B	B	B	A	247	280	A	C	C	B	51	A
55	0	26	A	B	B	A	A	A	B	B	245	279					19	C
57	0	21	E	A	B	A	A	B	B	B	250	273	A	B	C	A1	44	B
59	0	23	C	A	A	A	A	A	B	B	254	253	A	B	C	B	52	A
61	0	22	A	B	A	A	A	A	B	A	246	280					30	C
63	0	20	E	A	A	C	B	B	B	B	245	285	A	B	C	A1	20	C
65	0	24	B	A	B	B	A	A	B	B	249	280	A	C	C	B	46	B
67	0	27	A	B	B	A	A	A	B	B	253	276	A	C	C	B	48	B
69	0	26	B	A	A	A	A	A	B	B	253	280	A	C	C	A	34	B
71	0	23	B	A	A	A	A	A	B	B	248	280					41	B
73	0	24	C	C	B	A	A	A	B	B	245	279	A	C	C	A1	33	C
75	0	29	A	A	B	A	A	C	B	B	253	277	A	C	C	B	51	A
77	0	26	D	A	A	A	B	C	B	B	252	274	A	C	C	B	51	A

79	0	24	D	A	B	A	A	B	B	B	247	280					41	B
81	0	19	D	A	A	A	B	C	B	B	251	275	A	C	C	A4	35	B
83	0	21	C	C	B	A	B	B	B	A	245	280	A	C	C	B	48	B
85	0	22	C	A	B	A	A	B	B	B	257	267	A	C	C	B	50	B
87	0	24	A	B	B	A	A	A	B	A	246	281	A	C	C	B	48	B
89	0	22	E	C	A	A	B	C	B	B	254	286					46	B
91	0	21	B	A	B	C	B	A	B	B	256	277	A	C	C	B	46	B
93	0	29	A	B	B	B	A	A	B	A	255	276	A	C	C	B	51	A
95	0	25	C	C	A	A	A	B	B	B	249	263	A	B	C	A1	20	C
97	0	23	D	A	A	A	B	B	B	B	246	281					33	C
99	0	26	B	A	B	A	B	A	B	B	258	274					47	B

PIN	Group	onset of labor	nature of progress of labor	oxytocin	dose	drop rate	prostaglandin	ARM	Mode of delivery	nature of vaginal delivery	nature of expulsion of placenta	total duration of labor (from active stage)(IN MIN)	duration of 1st stage of labor	2nd stage	3rd stage	any sign of PPH
2	1	A	B	A	2.5	64	B	B	A	A	A	397	350	40	7	B
4	1	A	B	A	2.5	16	B	B	A	B	A	345	300	35	10	B
6	1	A	B	A	2.5	8	B	B	A	A	A	312	272	35	5	B
8	1	B	B	A	2.5	32	B	A	B	A	B	397	300	90	7	B
10	1	A	B	A	2.5	16	B	B	A	A	A	335	290	40	5	B
12	1	B							C							
14	1	A	B	A	5	64	B	B	A	C	A	387	340	42	5	B
16	1	A	B	A	2.5	32	B	A	A	A	A	355	300	50	5	B
18	1	A	B	A	2.5	16	B	B	A	A	A	325	290	30	5	B
20	1	A	B	A	2.5	64	B	B	A	B	A	357	310	40	7	B
22	1	A	B	A	2.5	54	B	B	A	B	A	325	270	45	10	B
24	1	A	B	A	2.5	32	B	B	A	A	A	350	300	45	5	B
26	1	B	B	A	2.5	54	B	B	A	A	A	340	305	30	5	B
28	1	B	B	A	2.5	32	B	A	A	A	A	360	315	40	5	B
30	1	A	B	A	2.5	32	B	B	A	A	A	388	333	47	8	B
32	1	A	B	A	2.5	36	B	B	A	A	A	348	305	38	5	B
34	1	A	B	A	2.5	16	B	B	A	A	A	305	270	30	5	B
36	1	A	B	A	2.5	48	B	B	A	A	A	390	315	65	10	B
38	1	A	B	A	2.5	64	B	B	A	D	A	388	335	38	15	B
40	1	A	B	A	2.5	54	B	B	A	A	A	400	350	40	10	B
42	1	A	B	A	2.5	30	B	B	A	A	A	415	365	40	10	B
44	1	A	B	A	2.5	30	B	B	A	D	A	415	365	40	10	B
46	1	A	B	A	2.5	16	B	B	A	D	B	385	330	40	15	B
48	1	A	B	A	2.5	32	B	B	A	D	A	370	335	25	10	B

50	1	A	B	A	2.5	40	B	B	A	A	A	355	300	45	10	B
52	1	A	B	A	2.5	32	B	B	A	A	A	365	330	30	5	B
54	1	B	B	B					C							
56	1	A	B	A	2.5	16	B	A	A	A	A	385	360	20	5	B
58	1	B	B	A	2.5	16	B	B	A	A	A	345	300	40	5	B
60	1	A	B	A	2.5	8	B	B	A	A	A	383	335	45	3	B
62	1	A	B	A	2.5	32	B	A	A	B	B	375	310	60	5	B
64	1	A	B	A	2.5	8	B	B	A	A	A	340	270	35	5	B
66	1	A	B						C							
68	1	A	B	A	2.5	64	B	A	A	C	A	425	390	30	5	B
70	1	A	B	A	2.5	16	B	B	A	A	B	370	310	40	15	B
72	1	B	B	A	2.5	16	B	A	A	C	A	440	405	30	5	B
74	1	A	B	A	2.5	8	B	B	A	A	A	414	353	54	7	B
76	1	A	B	A	2.5	30	B	B	A	D	A	345	300	35	10	B
78	1	B	B						C							
80	1	A	B	A	5.00	64	B	B	A	A	A	377	360	15	2	B
82	1	A	B	A	2.5	32	B	B	A	A	A	397	365	30	2	B
84	1	B							C							
86	1	A	B	A	2.5	16	B	B	A	D	A	260	240	15	5	B
88	1	B	B	A	2.5	16	B	A	A	C	A	440	405	30	5	B
90	1	A	B	A	2.5	8	B	B	A	A	A	410	350	49	7	B
92	1	A	B	A	2.5	64	B	A	A	C	A	425	390	30	5	B
94	1								C							
96	1	B	B	A	2.5	16	B	B	A	A	A	353	305	43	5	B
98	1								C							
100	1	A	B	A	2.5	32	B	B	A	A	A	394	362	30	2	B
1	0	A	B	A	2.5	40	B	B	A	B	A	555	420	120	15	B
3	0	A	B	A	5	64	B	A	A	B	B	560	440	115	5	B
5	0	A	B	A	2.5	64	B	A	A	A	A	315	240	60	15	B
7	0	A	B	A	2.5	64	B	B	B	C	B	440	365	60	15	A
9	0	B	B	A	2.5	48	B	B	A	A	A	390	300	75	15	B
11	0	A	B	A	2.5				C							

15	0	A	B	A	2.5	64	B	B	A	A	A	395	330	45	20	B
17	0	B	B	A	2.5	64	B	A	A	A	A	495	360	90	5	B
19	0	A	B	A	2.5	64	A	B	A	A	A	445	390	45	10	B
21	0	A	B						C							
23	0	A	B	A	2.5	54	B	B	A	A	A	490	360	125	5	B
25	0	B							C							
27	0	A	B	A	5	64	B	B	A	C	A	500	360	135	5	B
29	0	B	B	A	2.5	64	B	B	A	A	A	495	360	90	5	B
31	0	A	B	A	2.5	54	B	B	B	A	A	480	350	120	10	B
33	0	B	B	A	2.5	48	B	B	A	D	A	515	390	120	5	B
35	0	B	B	A	2.5	64	B	B	A	A	A	460	355	95	10	B
37	0	A	B	A	5	54	B	B	A	C	A	520	370	140	10	B
39	0	A	B	A	2.5	32	B	B	A	A	A	490	330	150	10	B
41	0	A	B	A	2.5	32	B	B	A	A	A	490	330	150	10	B
43	0	A	B	A	5	54	B	B	A	A	A	465	350	105	10	B
45	0	A	B	A	2.5	32	B	B	A	D	A	545	390	150	5	B
47	0	A	B	A	5	70	B	B	A	C	C	470	330	120	20	B
49	0	A	B	A	2.5	60	B	B	A	A	A	500	350	150	10	B
51	0	A	B	A	2.5	30	B	B	A	B	B	525	390	120	10	B
53	0	B	B	A	2.5	64	B	A	A	A	A	455	405	45	5	B
55	0	A	B						C							
57	0	A	B	A	2.5	32	B	A	B	C	A	437	330	105	2	B
59	0	A	B	A	2.5	64	B	B	A	A	A	443	350	90	3	B
61	0	B	B						C							
63	0	A	B	A	2.5	54	B	B	A	C	B	480	420	45	15	A
65	0	B	B	A	2.5	32	B	B	A	B	A	400	360	30	10	B
67	0	A	B	A	2.5	16	B	A	A	A	A	378	345	30	3	B
69	0	B	B	A	5	64	B	B	A	A	A	453	390	60	3	B
71	0	B	B						C							
73	0	A	B	A	2.5	64	B	B	A	A	A	430	390	30	5	B
75	0	B	B	A	2.5	48	B	B	A	D	A	515	390	120	5	B

77	0	A	B	A	2.5	64	B	A	A	A	A	315	240	60	15	B
79	0	A	B	A	2.5				C							
81	0	A	B	A	2.5	54	B	B	B	A	A	480	350	120	10	B
83	0	B	B	A	2.5	16	B	A	A	C	A	440	405	30	5	B
85	0	A	B	A	2.5	32	B	B	A	A	A	490	330	150	10	B
87	0	B	B	A	2.5	16	B	A	A	C	A	440	405	30	5	B
89	0															
91	0	B	B	A	2.5	32	B	B	A	B	A	400	360	30	10	B
93	0	B	B	A	2.5	48	B	B	A	D	A	511	390	119	2	B
95	0	A	B	A	2.5	54	B	B	A	C	B	480	420	45	15	A
97	0		B						C							
99	0		B						C							